THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE CENTERS FOR DISEASE CONTROL AND PREVENTION NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at The Garden Plaza Hotel, 215 South Illinois Avenue, Oak Ridge, Tennessee, on May 20, 2003.

VOLUME II

CONTENTS

May 20, 2003

| REGISTRATION AND WELCOME Dr. Paul Ziemer, Chair |
|---|
| ETHICS FOR SPECIAL GOVERNMENT EMPLOYEES Ms. Paula Kocher, HHS, OGC |
| EPIDEMIOLOGICAL RESEARCH OF DOE WORKERS - STATUS Dr. David Utterback, NIOSH |
| BOARD DISCUSSION/WORKING SESSION REVIEW PROCESS OF COMPLETED DOSE RECONSTRUCTIONS363 |
| PUBLIC COMMENT PERIOD |
| REVIEW/APPROVAL OF MINUTES, BOARD WORK SCHEDULE & ADMINISTRATIVE HOUSEKEEPING Ms. Cori Homer, NIOSH; Dr. Paul Ziemer, Chair; Mr. Larry Elliott, Executive Secretary |
| ADJOURN |
| COURT REPORTER'S CERTIFICATE |

TRANSCRIPT LEGEND

The following transcript contains quoted material. Such material is reproduced as read or spoken.

In the following transcript a dash (--) indicates an unintentional or purposeful interruption of a sentence. An ellipsis (. . .) indicates halting speech or an unfinished sentence in dialogue or omission(s) of word(s) when reading written material.

In the following transcript (sic) denotes an incorrect usage or pronunciation of a word which is transcribed in its original form as reported.

In the following transcript (phonetically) indicates a phonetic spelling of the word if no confirmation of the correct spelling is available.

In the following transcript "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

In the following transcript "*" denotes a spelling based on phonetics, without reference available.

In the following transcript (inaudible) signifies speaker failure, usually failure to use a microphone.

PARTICIPANTS

(By Group, in Alphabetical Order)

BOARD MEMBERS

CHAIR

ZIEMER, Paul L., Ph.D. Professor Emeritus School of Health Sciences Purdue University Lafayette, Indiana

EXECUTIVE SECRETARY

ELLIOTT, Larry J.

Director, Office of Compensation Analysis and Support National Institute for Occupational Safety and Health Centers for Disease Control and Prevention Cincinnati, Ohio

MEMBERSHIP

ANDERSON, Henry A., M.D. Chief Medical Officer Occupational and Environmental Health Wisconsin Division of Public Health Madison, Wisconsin

ANDRADE, Antonio, Ph.D. Group Leader Radiation Protection Services Group Los Alamos National Laboratory Los Alamos, New Mexico

DeHART, Roy Lynch, M.D., M.P.H. Director The Vanderbilt Center for Occupational and Environmental Medicine Professor of Medicine Nashville, Tennessee

ESPINOSA, Richard Lee Sheet Metal Workers Union Local #49 Johnson Controls Los Alamos National Laboratory Espanola, New Mexico GIBSON, Michael H.
President
Paper, Allied-Industrial, Chemical, and Energy Union
Local 5-4200
Miamisburg, Ohio

GRIFFON, Mark A.
President
Creative Pollution Solutions, Inc.
Salem, New Hampshire

MUNN, Wanda I. Senior Nuclear Engineer (Retired) Richland, Washington

OWENS, Charles L.
President
Paper, Allied-Industrial, Chemical, and Energy Union
Local 5-550
Paducah, Kentucky

PRESLEY, Robert W. Special Projects Engineer BWXT Y12 National Security Complex Clinton, Tennessee

ROESSLER, Genevieve S., Ph.D. Professor Emeritus University of Florida Elysian, Minnesota

STAFF/VENDORS

CORI HOMER, Committee Management Specialist, NIOSH STEVEN RAY GREEN, Certified Merit Court Reporter

AUDIENCE PARTICIPANTS

ADLER, TIM AHRENHOG, STEVEN APOSTOAEI, A. IULIAN AYERS, R.L. BELL, GLENN BILLARD, JOHN BROCK, DENISE DEHART, JULIA HENSHAW, RUSS HILL, JEFF HINNEFELD, STU HOFFMAN, OWEN HOMOKI-TITUS, LIZ HOWARD, JOHN HOFF, JENNIFER JESSEN, KARIN KATZ, TED KOCHER, DAVID LAWSON, JACOB HOWARD LEWIS, MICHAEL MILLER, RICHARD NAIMON, DAVID NETON, JIM POTTER, HERMAN POWELL, STEVE PRESLEY, LOUISE SCARBROUGH, CARL SCHAEFFER, D.M. SLOVAK, ANDY STEWART, JOHN SUNDIN, DAVE TABOR, BOB TANKERSLEY, BILL THOMAS, BRIAN TURCIC, PETE UTTERBACK, DAVID WILEY, ALBERT YIIN, JAMES ZIEMER, MARILYN

PROCEEDINGS

(8:00 a.m.)

REGISTRATION AND WELCOME

CHAIR

DR. ZIEMER: Good morning, everyone. While the Board members are finding their seats -- and I'm taking a quick count to make sure we have a quorum -- wandering around here a bit, but we're going to follow our agenda fairly closely, if we can, to try to stay on schedule. I do want to make a brief announcement, remind everyone if you have not done it to register attendance. Even if you did that yesterday, you should do it again today. We register the attendance for each day, so please do that.

Also members of the public who wish to address the Board during the public comment period, please sign up for that in the book that's back on the table.

We begin our session today with a presentation by Paula Kocher, who's Deputy Legal Adviser in the Office of General Counsel for Centers for Disease Control, and she also serves in a similar capacity for the Agency

for Toxic Substances and Disease Registry, ATSDR. I think the most interesting thing about Paula, other than being Deputy Legal Adviser, she has to oversee the work of 18 attorneys, and that's the -- that's the biggest challenge in the job, I think.

Paula, we're glad to have you here today, and she's going to address us on ethics for Special Government Employees. Which means ethics for members of this Board, is what that translates to. And this is -- if you want to call it training. It's required by FACA for people in our capacity, so we have to do this on a periodic basis.

ETHICS FOR SPECIAL GOVERNMENT EMPLOYEES

MS. KOCHER: Good morning. First I just wanted to say that I had the privilege of meeting David Kocher yesterday. It's highly unusual to come to a meeting with my last name and meet someone else who's speaking with the same last name, but he is not my long-lost second cousin, so...

I'm actually here today to both congratulate and thank you for agreeing to be and being selected for membership on the Advisory Committee on Radiation and

Worker Health. As is stated in the Committee charter, you are charged with advising the Secretary of Health and Human Services on the probability of causation guidelines, the dose reconstruction and Special Exposure Cohort rules, and review of SEC petitions. But with these responsibilities come two sets of rules, and that is what I will be primarily talking to you about this morning.

In a nutshell, you are required to follow a standard of conduct as a Special Government Employee. For instance, you must not, generally speaking, accept gifts because of your official position, or share non-public information with outside sources.

For those of you with a financial interest in the matters that come before this Committee, you must take certain steps to avoid a conflict of interest. And as a Special Government Employee you must act impartially towards members of the public, and there are limits on your representing others before the Department of Health and Human Services or the Department of Labor relating to radiation compensation claims.

The second set of rules is derived from the Federal

Advisory Committee Act. My understanding is that you all received a copy of a videotape. Did any of you have a chance to look at it? Wonderful. You might recognize somebody. Another attorney and I put that tape together -- oh, I guess it's probably about six or seven years ago, and I do recommend it because not only does it review some of the rules that we'll go over this morning, but I think it gives a very nice historical perspective about the Federal Advisory Committee Act, and the importance of Federal advisory committees in general.

FACA's overriding purpose is to make consensus advice to the Federal government from people outside the government as transparent as possible. That is why your meeting today was announced in the Federal Register. It's why minutes of the proceedings are being kept, why a Federal official such as Larry Elliott is present, and why this meeting is open to the public. As a member, you have a responsibility to ensure that your deliberations comply with FACA. You can certainly communicate with each other outside this public forum, for instance, to exchange factual

information. But you should avoid even the appearance that you are conducting Committee business, deliberating and reaching consensus when you're not seated at this table with a Federal official present. I'll go into more detail about those obligations in a minute.

So let's begin reviewing these two sets of rules. I will finish up by also talking about -- a little bit about the Privacy Act and the Freedom of Information Act. And we're going turn to the Power Point now, and I wish to thank Liz Homoki-Titus for putting the Power Point together for me.

Can you still hear me okay? Sort of? I'll try to speak up. Almost have to be out here to see this.

DR. ZIEMER: That's fine, you're good. Stay there.

MS. KOCHER: Stay right here?

DR. ZIEMER: Uh-huh.

MS. KOCHER: Okay. Let's define what a Special Government Employee is. Well, it's an officer, an employee in the Executive Branch of the Federal government, and you're appointed to perform temporary duties, with or without compensation, for a period not

to exceed 130 days during the previous year. All the Board members here are Special Government Employees. One of the most important rules has to do with conflicting financial interests. And under Title 18 of the United States Code, Section 208, a Special Government Employee may not act in certain matters that would affect the financial interests of the Special Government Employee or their spouse, minor children, general partner or an entity they serve as officer, trustee or employee. And just as an aside, the rules have set \$15,000 or less as the amount that's not considered a conflict if you own stock from one source. So how do we deal with a conflicting financial interest? Well, as most of you know, you are able to get a waiver, and many of you here at this table probably have a waiver memo, and that's available if the Department determines that the need for your service is actually greater than the conflict. And what that waiver basically does, it allows you to deal with matters of general applicability. Now there may be situations where you would actually have to disqualify or recuse yourself from deliberations of the

10

11

12

13

14

19

16

17

18

19

20

21

22

committee when there is a specific matter -- excuse me, a particular matter between specific parties that's being deliberated that would affect your financial interest.

Let's look at the example here. If a Board member owned \$30,000 of Oak Ridge Associated Universities stock, he would either have to get a waiver or divest that stock in order to serve on the Board. Well, obviously divesture is probably the least attractive option, and that's something that we'll rarely ever even have to think about.

What's an appearance of a conflict of interest? Well, the standard is if the circumstances would cause a reasonable person to question the Special Government Employee's impartiality, then there is an appearance of a conflict of interest.

The example that's given here, if four members of the Board were to meet with a member of the public for lunch during a Board meeting, there could be an appearance of a conflict of interest to other members of the public who do not receive such personal special access to the members of the Board. And we look to the

standards of conduct found at Title 5 of the Code of Federal Regulations, this handy little book right here -- this is not all the rules. Okay? Just a small portion of this deals with these rules today. But this one says that an employee shall act impartially and not give preferential treatment to any private organization or individual.

Gifts, illegal gratuities and bribes. Well, may you accept a gift? In most instances not. Certainly when the gift is given because of your official position, and we look to see whether or not the giver of the gift has a connection with the agency seeking action, seeking to do business, already conducts business regulated by the agency or has interests affected by how you perform your duties. But it is okay to accept occasional gifts, as long as they're valued under \$20 and the aggregate does not exceed \$50 from one source in a year.

There are other exceptions that are listed in the standards of conduct that I won't go into -- fairly common sense sort of things, where you have a personal relationship with someone.

Here's our example. Mr. A, who's president of XYZ Corporation, offers the Advisory Board member a new set of golf clubs, if -- if -- if the Advisory Board member will support XYZ's bid for the contract to assist the Board in its work. Now obviously Dr. B cannot accept the gift, and this is an easy one.

But sometimes there are situations that come up that are not quite as clear as that, and so what I would do is I would urge you to contact Larry or David or Liz and talk some of these issues over with them. have an attorney in Washington D.C. who only deals with ethics issues, and sometimes we'll -- I mean we'll be able to consult with him, as well. Of course what this is all about is a criminal matter found in Title 18. Use of non-public information. This is an important Information that's learned due to your government one. position that is not publicly available may not be used to further your, or anyone else's, financial interests, or be shared with outside sources for any reason. Here's our example. The Board is told that, once again, XYZ Corporation has been selected for a contract to review dose reconstructions, but the public

10

11

12

13

14

19

16

17

18

19

20

21

22

announcement will not be made for a couple of weeks.

Board members may not use this information for anyone's financial gain, nor tell non-members this information for any reason, and the authority for this is found in the Code of Federal Regulations, Title 5, which states that employees shall not allow the improper use of non-public information to further his own private interests or that of another, whether through advice, recommendation or by knowing, unauthorized disclosure.

(Pause)

All right, moving right along. Outside activities. This really just means that you cannot accept compensation for being a Board member here today. Of course you're -- may of you are employed. You will continue to receive that salary. You will do so while you serve as a Special Government Employee for the government. There's an exception that's made for Special Government Employees who do serve on advisory committees. But the only compensation that you can receive for serving as a Board member is from the Federal government.

Now in the second bullet it talks about compensation

being allowed for activities that are related to your Board service, and you can of course continue to write or make speeches where you have a brief discussion of the work that you do here on the Board.

Let's look at the example. Dr. C on the Board is asked to speak at the annual meeting of a private organization. He cannot get paid to discuss his work on the Board, but he can speak, for a fee, if he is discussing his own private research and only briefly discusses the publicly available information about the Board's work. And we look for authority again to Title 5 of the Code of Federal Regulations where it states that an employee shall not use his public office for his own private gain, or for the private gain of friends, relatives or persons with whom the employee is affiliated in a non-governmental capacity.

There are some employment restrictions placed on Special Government Employees as to their work on the Board, so a Special Government Employee cannot work on matters that would affect the financial interests of a current or future employer. And this goes back to what I was saying before dealing with conflicts of interest

and seeking a waiver. But there are instances where you literally cannot get a waiver and again you have to recuse yourself from the discussion that was going on. And what I would suggest everyone do is, prior to coming to a Committee meeting, check the agenda, look it over, see if there's anything on there that would make you believe that there's going to be something that will definitely affect your financial interests. And again, seek counsel from Larry, who can then talk with David and Liz, and we can figure out how best for you to approach the situation.

Post-employment. So you leave the Board and you think well, that's it; I'm done, I don't have to worry about these silly standards of conduct anymore. Well, that's not entirely true. There are still restrictions on your being able to represent another person -- not yourself, but another person or entity back to the Federal government. But it's in a -- it's in a very narrow area where there's a particular matter involving a specific party in which you participated personally and substantially while you were serving the government.

There are a couple of other rules related to limits on representation, and this one has to do with when the United States is a party or has a direct and substantial interest. And again you will have had to have participated personally and substantially. You are also once again urged to contact the Department. If you have any kinds of questions we'll be happy to help you through this. Many of these issues are very fact-specific. We really need to understand the facts in order to be able to advise you.

But the example that's given here, a Board member may not represent a petitioner for the Special Exposure Cohort, even on an unpaid basis.

This is yet another one that basically just points out that -- here the example is that not even the business partner may represent a petitioner when compensation is being offered.

Okay. Let's move from the standards of conduct to the Federal Advisory Committee Act. And again, the most important thing to remember about FACA is that it promotes open and public meetings. And as you know, each advisory committee meeting shall be open to the

public.

Now there are instances where meetings have to be closed because there will be deliberation about non-public information. But even so, that still has to be announced in the Federal Register. The public has to be notified that that meeting is going to take place.

And as you well know, interested persons -- or non-interested, for that matter -- shall be permitted to attend, appear or file statements with any advisory committee. And it seems to me that what's happening here is that there's a public comment period every day of a Committee meeting, which is wonderful.

Also the documents that were made available or prepared

Also the documents that were made available or prepared for by each advisory committee shall be available for public inspection and copy. And as I learned yesterday, many of the things are being placed on a web site, so it's really made available to the public. You don't even have to file a Freedom of Information Act request.

Minutes of each meeting of the advisory committee shall be kept, and one thing many people don't realize is that the Chair must review those minutes for their accuracy and certify that they are in fact accurate.

And very importantly, advisory committees shall not hold any meetings except at the call of or with the advance approval of the committee's designated Federal official, Larry Elliott in this case.

I'm going to talk a little bit about the Privacy Act because it will be implicated in the work that you all do here. The Privacy Act prohibits disclosure of personally-identifiable information to any third party without the written consent of the individual to whom the record pertains, unless one of several statutory exceptions applies. I won't get into those other than to say they're things like audits that are being done by the Inspector General, if there is actually a court order issued -- a court that has what's considered competent jurisdiction over the matter, but otherwise you've got to have consent.

It is the policy of the Department to protect the privacy of individuals to the fullest extent possible, while at the same time permitting the exchange of records so that you all can do your business. And it's also the policy that the Department be as open as

possible and fully comply with the Freedom of
Information Act and the requests that are made under
that Federal statute.

Here's the bottom line rule for the Privacy Act. Do not discuss individual claims with any non-government employees or with government employees who do not have a need to know the Privacy Act-protected materials.

And please understand that there are both civil and criminal penalties that apply to this Federal law for any knowing violations.

Let's look at a couple of -- I thought we had an example. I guess we don't here.

Privacy Act rules. These are not just rules for the Privacy Act, but these are also, just generally speaking, good rules for Special Government Employees.

Don't speak for the agency or the Board. Avoid discussing or disclosing the merits of individual claims -- and I cannot emphasize that enough, and let me just say also, you need to be very careful when you do have claims information that's personally-identifiable to make sure that it's locked up at all times, that it's -- it's not something that you should

carry around casually. I wouldn't put any of that information in an e-mail -- e-mails are not secure. So you really do need to be vigilant when it comes to handling Privacy Act records. Stick to public information and refer requests to OCAS. Avoid speculating about the identity of a claimant. Avoid speculation about dose reconstruction issues. Don't try to predict future agency or Board actions. You need to avoid assisting with individual claims, but you -- under the standards of conduct, you are able to serve as a fact witness for some of these claims if you happen to have been an employee at the time with this coworker who's filing a claim.

Here are my examples. So here's two. So we have two
Board members who are talking about someone's dose
reconstruction and the gentleman's office is open. His
coworkers can overhear his conversations. This would
be considered a violation of the Privacy Act because
that information may not be shared with non-government
employees.

Another example is where an Advisory Board member has been reviewing information on the computer tracking system and he goes ahead to print some files to review later. He leaves them on his desk. Again, this is a violation of the Privacy Act because the information must be protected to ensure that only government employees with a need to know have access to that information. That would be easy to take care of. Just put it in a file drawer and lock it or lock the door when you leave.

Just a short statement or two about the Freedom of Information Act. It is a disclosure statute. It is a way that people are able to get access to government documents. There are some statutory exemptions. One of the ones that we're finding to use more and more at CDC now has to do with security issues, which you can understand. But records are available to the public under the Freedom of Information Act. Again, what I—what's happening more and more is that the government is putting things on the web site and making things much more accessible to people so they don't have to go ahead and file that FOIA request. But the Department does answer all written requests for records.

With regard to media and Congressional inquiries, here

are just some guidelines to be thinking about. You can always refer media inquiries to Fred Blosser, who is with NIOSH. And Congressional inquiries -- I mean Larry loves to get them, don't you, Larry? Yeah, he lives for those Congressionals. You know, if you do choose to speak to the media, you know, make clear that you're speaking as an individual and not for the agency or the Board. And please limit yourself to public information. Remember the standard of conduct I talked about, not disclosing non-public information. And it's always a good idea to say that's what you're doing. You know, I'm telling you what is already publicly known, this is it, so it's very clear to the media that that's what you're doing. And again, you know, Fred -this is what he does for a living. And Larry, I think this is what he does for a living, so you know, feel free to contact them and see if you can coordinate any response you're going to make -- be making with the agency. And here's some contact information that I think you all have as part of the Power Point slides that were given to you.

10

11

12

13

14

19

16

17

18

19

20

21

22

I think that's it. Thank you very much for your time.

DR. ZIEMER: Thank you very much, Paula. I suspect there might be some questions.

MS. KOCHER: Sure.

DR. ZIEMER: Let's see if there are. I'm going to ask one. Let me ask it in the form of a hypothetical situation. Let's suppose that the Florida chapter of the Health Physics Society invites Dr. Roessler to come down there and give a talk to their chapter about the work of this Board. She can't accept any payment for this. Can they cover her travel expenses?

MS. KOCHER: We have what are called travel regulations. I would have to look at those, and I would be happy to do that because they're very specific. So without having the rules with me, I wouldn't want to, you know, guess --

DR. ZIEMER: Well, it would seem to me that that's a fairly likely scenario for some members of this Board, as opposed to a payment or honorarium --

MS. KOCHER: Well, let me ask you this. Are you going down to do things other than just talk about your Board membership and --

DR. ZIEMER: If she were invited to Florida, she would,

but --

10

11

12

13

14

15

16

17

18

19

20

21

22

DR. ROESSLER: This actually hasn't happened, but it is -- it's a really likely scenario, and I -- I would ask you to look at it from the point of view that there is nothing else. It would just be to attend the meeting, because I think it's a reasonable --

MS. KOCHER: No, what I mean is your attendance at the meeting, are you being invited because you're an Advisory Board member and you're expected only to address issues --

DR. ZIEMER: That -- yes.

MS. KOCHER: -- related to the Advisory Board, or because of your other expertise or other research or writing that you've been doing?

DR. ROESSLER: Let's assume that it's just as an Advisory Board, and let's also assume that if I couldn't go, Dr. Ziemer would go.

MS. KOCHER: Okay.

(Laughter)

DR. ZIEMER: And if I couldn't go, Wanda would go. No, I think it's -- I think it's --

MS. KOCHER: Yeah.

DR. ZIEMER: -- a fairly likely expectation that members of this Board might be asked to tell what the Board's doing -- it would be analogous to our colleagues from Great Britain coming here to talk to this group. Maybe not analogous 'cause I don't know if they're -- who paid for their transportation, but -- but an invitation of that sort, tell us about what the Board does.

MS. KOCHER: It's a great question --

DR. ZIEMER: We could always say Larry will come and tell you.

MS. KOCHER: It's a great question, and what I'd like to be able to do is talk with David and Liz and we'll get an answer back to you. And we can do that so it's for the entire Board then.

DR. ZIEMER: Thank you, that would be helpful. Other other questions or comments?

MS. KOCHER: And if you have any individual questions that you don't want to raise now, you know, you can ask me on the break, as well. Okay. Thank you.

DR. ZIEMER: Hold on, Paula, just a second.

MR. ELLIOTT: I'm just going to let the Board know that

because the overhead -- or the slides that were placed in your booklet are a little hard to read, some of the fonts small, we will send this by e-mail to you all so that you have a copy that you can read from.

DR. ZIEMER: Good, thank you. Thank you again, Paula.

MS. KOCHER: Uh-huh.

EPIDEMIOLOGICAL RESEARCH OF DOE WORKERS - STATUS

DR. ZIEMER: Okay, we're going to move ahead on the schedule. We're pleased to have two individuals actually, and Dr. Utterback is going first, I understand. Mary Schubauer-Berigan has been with us before, but who -- who's going first?

DR. SCHUBAUER-BERIGAN: Dr. Utterback.

DR. ZIEMER: Okay. Well, Dr. Utterback is Chief of the Health-related Energy Research Branch at National Institutes for Occupational Safety and Health in Cincinnati. He really originally was an industrial hygienist, and maybe still is in that regard, but he has responsibilities on the U.S. Department of Energy Occupational Epidemiology studies at Idaho National Engineering Laboratory and other DOE sites, and he also has been involved in a number of these epidemiological

studies that have been funded through DOE to Health and Human Services.

He has been very active in a number of professional activities related to this, and I'm not going to read his whole biographical sketch, but there is a copy of it on the table and you can avail yourself of that.

We're pleased to have Dr. Utterback with us today to speak on the epidemiological research of DOE workers.

Dr. Utterback.

DR. DAVID UTTERBACK, NIOSH

DR. UTTERBACK: Thank you for the introduction, and thank you for the invitation to be here. It's truly a pleasure to be here and talk about our research program at the National Institute for Occupational Safety and Health that evaluates the health of workers who have been employed at Department of Energy sites.

With me today is Mary Schubauer-Berigan, and we've divided this presentation up. Mary's presentation will follow mine and I'll try to set the stage for her, and she is to go through our research program and describe it in such a way that it addresses some questions that we understand that this Board had concerning the way

that the NIOSH research program addresses the issues related to compensation of workers.

The NIOSH program on the health-related energy research came into existence in 1991, and our group -- at that point in time a core group was on board, beginning to get things organized, and in 1992 they were able to hire a number of additional scientific staff to get a number of things underway. We are a group that conducts analytical epidemiologic studies of workers at Department of Energy sites. And we also get involved in a number of other activities related to these sites from time to time. The core of our mission is to conduct the analytic epidemiologic studies. We do this both through intramural and in extramural research program. The balance between the two historically -- it varies from year to year and it's certainly at one end of the spectrum right now, but about one-third of our dollars have gone out for extramural research grants and contracts and cooperative agreements. So we try to emphasize extramural research because we think it's a very

10

11

12

13

14

19

16

17

18

19

20

21

22

important way to allow the broadest range of intellects

to address these very complicated problems.

Our average funding over the years has been about \$5 million. We're once again kind of at a low point here, substantially below that \$5 million right now and have been for the last couple of years. And currently we have 27 FTEs available to us within the Branch to, you know, do the things that are necessary to have a program of this nature.

We came into existence -- actually the responsibilities for this type of research were transferred to HHS and the CDC as the result of a secretarial panel for DOE. This is the so-called SPEERA panel. You may have heard of this in the past; maybe this is a new acronym. It's the Secretarial Panel for Evaluation of Epidemiologic Research Activities at the Department of Energy. And at that point in time, in the late 1980's, there was quite a bit of concern about these studies that was coming out and the Secretary of Energy, Admiral Watkins at that time, convened this panel to try to address this issue. And they made a number of recommendations. One is that the epidemiologic program -- studies needed to be made independent of the Department. There is

some -- questions that were coming out about the credibility of these studies given that they were conducted by contractors to the Department of Energy, and there was a group at that time, the Physicians for Social Responsibility, that published a very thorough analysis, if you will, of these studies -- programs called Dead Reckoning. So the decision was made to transfer the responsibility for the epidemiologic program to the Department of Health and Human Services, and through that process it came to CDC, and NIOSH does the occupational studies. National Center for Environmental Health has been involved in the studies of populations around these sites.

They believed that by doing this they could restore public trust in the studies, and that it was the means to try to assure the highest scientific credibility or quality of these studies to put them into a research program, a research-oriented program where, you know, there was opportunities for peer review, thorough analysis of proposals that were written and those types of activities associated with research programs and HHS. And they were especially trying to ensure the

independence of the investigators, that these people could have the ability to request information and get the information necessary to do these studies and not be subject to some of the limitations perhaps that a contractor directly to the Department of Energy would have to prevail.

And we considered all these to be very important issues. Public trust, scientific quality, independence of investigators, stakeholder input, we want this to be an open process, and it is an open process. And you know, our studies go through peer review. CDC has recently instituted a policy now that every five years the research projects have to go through another round of peer review if they have not been completed in that period of time. So these are things that we take very, very seriously in the way that we organize and conduct our research program.

Here is our staff, and our scientific staff is on the left, the information technology staff in the upper right, and then our support staff in the lower right.

Now we have a number of industrial hygienists, health physicists, epidemiologists that work with our program

and conduct a lot of the science that gets done within this group of studies. In the upper right is our information technologists, and again, these people are vitally important to us and our success. We are very, very information system rich. It takes a tremendous amount of data and data manipulation and testing and evaluation in order for these studies to be successful, and so we have an excellent staff of information technologists that are really at the leading edge in a lot of this kind of research and putting together information systems necessary to conduct it. course our support staff, we wouldn't be here without them, so this is a great group of people that I work with. I'm truly very honored to be associated with them.

10

11

12

13

14

19

16

17

18

19

20

21

22

The research purpose is -- I've kind of paraphrased a few things here to make them fit on a slide, but this was something that we did together under Larry Elliott's leadership when he was the Branch Chief of this group, and we went into a strategic planning process and developed a mission statement, purpose and some research goals associated with that, and these

have been very helpful to us in trying to keep us on beam, keep us focused on what's important.

And overall we're primarily interested in understanding the risk of radiation in the occupational setting on worker health. How is it that the various forms of radiation that exist within the occupational environment, how do those impact a worker's health over their lifetime. And of course cancer is a primary response that we were concerned about, given the types of impact that it has on a person that suffers from one of these various types of disease. Grouped together they're called cancer. So we're interested in evaluating the significance of the health effects in the radiation-exposed workers. And by significance we're not just talking about, you know, the number of incident cases to the number of prevalence -- you know, the prevalence of the disease. We're interested in the impact it has on the individual and the worker's life and how that -- change is brought about in that individual's life as a result of that health effect. And we think it's very important that we have an informed public and an informed group of workers that

10

11

12

13

14

19

16

17

18

19

20

21

22

understand our studies. We work very hard with the communication effort to get our word out to the workers so that they can understand what the study is saying about their health and how their health may be affected in the future.

And it's important to recognize that it's not only radiation that we study, but also chemical and other stressors within the work environment. And we look -- as you'll hear more about today, that there are a variety of studies that try to look at multiple exposures, not just radiation.

Research goals. Again paraphrasing, trying to collapse these down into some succinct statements here. Again, to evaluate the relationships between work place exposures and diseases. And we wish to use and we try to use and we do apply the best available analytical methods with this. In order to apply the best analytical methods, you've got to have a top quality staff. And you know, we have many, many people in our group -- although it's a very, very small group, we have many, many people in our group that are very high quality scientists and we feel that, you know, we've

got the intellect necessary to try to determine which path to follow and how to get there, but it is something that requires, you know, input from our staff and their discussions that they have with colleagues in the scientific community and the like to try to build towards that goal.

We do want to analyze combined populations for rare cancers where, you know, one single population -- this is something I heard mentioned yesterday in one of the discussions about trying to get populations large enough for statistical analysis to be meaningful. And one of the ways that we've gone about this is to combine studies across sites so that we look at different populations, bring them together in order to have sufficient numbers to try to determine if there is an effect associated with an occupational exposure. And we've really become specialists at this. This is no simple task. When you talk about, you know, eight or ten data systems from each site that you're trying to bring in to apply to a study, and then you multiply that times the number of sites, all that linking and matching and testing and evaluation, it all

10

11

12

13

14

19

16

17

18

19

20

21

gets very, very complex and difficult to achieve. But we've really become specialists. This is our -- this is our cup of tea. This is the way that we try to address studies and try to bring meaningful results out of the research that we do conduct.

Again, we want to examine the relationships -exposures and worker health. I mean anybody that's worked in this field of environmental/occupational health for a period of time realizes that this has been an issue at the top of the agenda for decades. know, I hate to speak like I have that much experience in this, but I'm afraid to admit that I do now, having been in this field for 25 years. But the question has always been toxicologically epidemiologically well, this is what one compound does, but nobody gets exposed to one compound. So we're working trying to address that, look at multiple exposures, radiation in combination with other chemicals, chemicals in combination with other factors and stressors in the work place. But it takes very large datasets and systems and a good deal of time to get this accomplished.

10

11

12

13

14

19

16

17

18

19

20

21

And again, our bottom line is that we want to complete the epidemiologic research, which increases our understanding of the effects of low levels of exposure in the work place to ionizing radiation to DOE workers and others. There are -- research does have impact, meaning for other workers beyond the DOE sites, and we want that to be very clear, as well. There's a large impact that we feel we can have within the occupational health community because of the types of records that are available to us and the investment that's being made in this, and has been made in this program. There are a number of previous occupational radiation studies that have been completed. We've assembled a bibliography, an annotated bibliography, if you will, of studies that we feel are directly pertinent to the work that we do. You know, the previous studies at the weapons sites that go back, you know, into the sixties with Mancuso* and his colleagues at University of Pittsburgh, the DOD studies of shipyard, the nuclear Navy studies that are out there. And again, we heard some comments yesterday about the atomic veterans studies and compensation program. There's

10

11

12

13

14

19

16

17

18

19

20

21

international studies. There's a lot of attention and effort being focused on workers at Mayak, the plutonium facility in the former USSR. There's a very large multi-national studies being conducted by the International Agency for Research on Cancer under the leadership of Elizabeth Cardis*. Both Mary and I, you know, serve on subcommittees within that study and we are contributing data to that study. And then also there's been various studies of medical workers -- Xray technologists, radiologists and various physician specialties within the health care setting. Our purpose here today is, you know, to talk about the status of the HERB research program and to talk about how it fits into the questions that you've raised as a Board for us to address. And you know, basically what we're going to be driving towards is discussing the uncertainty in the current knowledge and how that has an impact on the models that are driven, trying to understand probability of causation for compensation of workers at these sites. So we want to further identify any research areas that you may have related to the compensation of these workers.

10

11

12

13

14

19

16

17

18

19

20

21

And I think all of us kind of join together in realizing that, you know, the work is not done here. There's a lot of current workers in the audience out here I believe, and I think all of us want to join together and work as hard as we can to try to protect the health of those current workers, and there's even a few current workers on the Board here. So I mean it really is a commitment that NIOSH has to try to protect the health of the American work force, and the DOE workers are a very important part of that and we consider that part of our mission, as well. So with that, I'll turn it over to Mary Schubauer-Berigan and she will begin to discuss -- present the status of our research program and talk about how it's related to the questions that you raised. Thank you.

10

11

12

13

14

19

16

17

18

19

20

21

22

DR. MARY SCHUBAUER-BERIGAN, NIOSH

DR. ZIEMER: While Mary is coming up -- she's there already, but let me just mention that she is the lead epidemiologist with the Health-related Energy Research Branch, division of surveillance, hazard evaluation and field studies within NIOSH. And she's been involved in conducting epidemiological studies of cancer and other

health effects among U.S. nuclear workers for a number of years now. So Mary, we're glad to have you back with us today.

DR. SCHUBAUER-BERIGAN: Thank you very much, Dr. I'd like to reintroduce myself to the Board. It's been about a year since I've been up here speaking before you, and now I'm wearing a different hat. been back for the last year or so working with the Health-related Energy Research Branch, continuing to conduct epidemiologic research on DOE cohorts. What I'm going to do, as Dr. Utterback mentioned, is to talk about our current epidemiologic research program and to try to place it into the context of what we understand to be the main issues that were raised by this Board in your last meeting in February. start with a discussion of some of our current studies. And the first slide illustrates several studies that are ongoing that are being conducted by our cooperators, either through contracts, grants or cooperative agreements. And these are listed primarily in the order in which we expect them to be completed. The first study that I'll mention is a study of Rocky

10

11

12

13

14

19

16

17

18

19

20

21

Flats workers. This is a cohort study conducted through a cooperative agreement with the Colorado Department of Public Health, Welfare and Environment, and through a grant that they have to Dr. James Ruttenber as lead investigator. Several studies have been completed and are near completion to date. We recently attended a communication of Dr. Ruttenber's results for a cohort mortality study and a lung cancer case-control study in Denver. And several of you may have heard some of the initial findings of that study. The report is available or shortly will be available on our internet web site. This also includes dose assessment of plutonium doses to lung, using the most current ICRP-60 methodology, and we're eagerly anticipating the findings of that study, as well. That is not quite as near to completion, according to our understanding.

10

11

12

13

14

19

16

17

18

19

20

21

22

There's also currently a grant through the University of North Carolina, Dr. Steve Wing, to study -- to further study the Hanford cohort mortality experience.

As many of you know, this is a very important cohort that's been studied quite extensively over a period of

decades. And Dr. Wing and colleagues anticipate their update to be completed and a report available sometime we believe this summer.

We also have a grant with the University of Cincinnati. Dr. Susan Pinney and Richard Hornung, who many of you are familiar with as well, are studying additionally radon, cigarette smoking and their interaction on lung cancer risk among workers at the Fernald facility in We anticipate -- we've been in contact with Ohio. these researchers fairly recently and we do anticipate a study report sometime before the end of this fiscal We believe this will be a very important study as it uses new techniques to try to address missed information on cigarette smoking that could help address issues of the interaction between radon exposures and smoking in producing lung cancer risk. We have a contract through ORAU with Janice Watkins, who is subcontracting with Ed Frome, to further evaluate time-related factors that are of importance in evaluating cancer risk. Right now this is primarily restricted to the Oak Ridge National Lab cohort. anticipate the final report will be finalized sometime

10

11

12

13

14

19

16

17

18

19

20

21

before the end of this fiscal year, as well. And this contract is looking further into some of the issues regarding age at exposure, time since exposure and just how one models complex epidemiologic data to disentangle the various effects of time-related factors.

We have a new grants program, as well, that has funded two studies, one of which is listed here, a grant with Dr. David Richardson, also of the University of North Carolina. And this is looking at susceptibility, time-related risk factors and occupational radiation risks at the Savannah River site cohort. This was just recently funded and data has begun to be processed, we understand, by these researchers. We anticipate the completion date therefore will be sometime within the next several years.

Not on this slide but of great importance to us are several other projects that I just wanted to mention. There's a very large ongoing study now of the Paducah workers, and this is being conducted by the University of Kentucky and the University of Louisville. Also recently funded through our grants program was a grant

to researchers at the University of Washington, who are looking at multi-stage modeling for lung and colorectal cancer in the Canadian National Dose Registry workers, and they also anticipate using data from CEDR, as well. We also have a grant that is closer to completion on dosimetry errors with Roy Schorr* and colleagues at the University -- or at New York University.

Next I'd like to talk about some of our current internal studies that are being conducted by the researchers that Dave mentioned on one of his slides. First we'll try to illustrate some of the cohort-based studies, what they're trying to evaluate and when we expect them to be completed. And again, these are listed approximately in the their order of expected completion.

We have several studies ongoing at the Portsmouth Naval Shipyard, and although this is not a DOE facility, it is of historic importance and of great current importance for several reasons. It's primarily a group of workers who were exposed to high energy photons, and so it's a great cohort to study issues related to that particular exposure. We don't tend to see a lot of

internal exposures and tritium and other factors, so it does provide -- in terms of radiation risk -- a fairly singular exposure, but yet it's a classic occupational setting in which exposures are received in a chronic rather than in an acute basis.

We have several reports soon to be issued for this cohort. I'd like to mention that several of the -- my colleagues, in addition to Dr. Utterback, are with us today in the audience, and if you have questions about them, I may defer to some of the investigators themselves who are with us, but I did want to acknowledge they're here, too.

We also -- I'll mention a couple of other studies that are of real importance in answering some of the key questions that we believe the Board has, and some of them pertain to this PNS facility, so please keep that study in mind.

We also have a large cohort study for a group of workers that we believe to be very important. It's a group of more than 60,000 workers at the Idaho National Engineering and Environmental Laboratory, and as Dr. Ziemer mentioned, both Dr. Utterback and I are

investigators, as well as Greg Macievic, in this study. These worker -- this work force is a very diverse work force consisting not only of radiation workers, but of workers who may have had more incidental access to the site, such as ranchers or farmers. We have workers who were involved in the construction of the facility, as well as processors and researchers, so it is a very diverse cohort. Approximately a half to a third of them do have radiation monitoring data, so we will be able to conduct dose response analyses. These analyses are underway and we expect to have a final report before the end of September for this cohort, as well. A third cohort-based study that I'd like to mention is a study of the chemical laboratory workers at four facilities within the DOE complex. These are the three facilities in Oak Ridge and workers at the Savannah River site. As your briefing document mentioned, very few studies have been conducted of workers in chemical laboratories, and this study we hope will address some very important issues with regard to interactions between chemical exposures. And the chemical exposures of primary concern here are workers who were employed

10

11

12

13

14

19

16

17

18

19

20

21

in inorganic, organic and organic mist labs, and Dr. Utterback is a primary author of that study, as well, and will be able to address any questions you have about that. This study is a little farther behind and we expect that to be completed sometime before the end of this calendar year, or perhaps in late winter.

Lastly we have a cohort study of Fernald workers, and this has been driven by questions related to uranium exposures across the complex. We do expect this study to address issues related to radon and lung cancer, as well. Dr. James Yiin, who is with us today, is the lead epidemiologist on that study. That is really in its early phases and we don't expect that to be completed for several years.

In addition we have several case-control studies, and for those of you who are not epidemiologists, in occupational settings we typically study cohorts, and we also study -- use a study design that is designed to be very efficient and yet very thorough in studying specific diseases. These are conducted in a case-control setting in which you take all of the cases that you see in a cohort and you select randomly from

eligible workers who didn't have the disease to study exposures in those two groups to determine if there's a difference between those with disease and without. It's a very efficient design because instead of studying 60,000 people, you can address the same issues by studying 1,000 or 2,000, which makes the exposure assessment much more thorough and much more costeffective.

Several case-control studies are currently ongoing to address specific important questions. We have a leukemia case-control study in the Portsmouth Naval Shipyard which is being conducted by Travis Kubale as part of his dissertation program, and he is with us today. We do expect this to be fairly close to completion, sometime before the end of this calendar year, and I know Travis would be very happy to have that sooner rather than later.

We have a second case-control study at the PNS facility which is looking at lung cancer risk. This was driven by observations in the first studies that had been conducted in this cohort in which excess risks of lung cancer were observed, but because of the rather high

asbestos exposures, and perhaps exposures to welding fumes that occurred at the facility, we anticipated the need to do a lung cancer case-control study to evaluate those three factors in addition to smoking. This study is approximately a year and a half away from completion, and several of the researchers on the PNS team are also involved in that case-control study. My second study is a multi-site leukemia case-control study. We've had this ongoing for several years now, and it combines workers from six different cohorts at five different DOE and DOD facilities, including Hanford, Savannah River site, Los Alamos -- including ZIA* workers, the Oak Ridge National Laboratory and the Portsmouth Naval Shipyard. This study has almost 260 cases of leukemia, which makes it one of the largest studies of its type ever conducted. But as you can imagine, conducting an exposure assessment at six -- or five different facilities is quite complex, given the number of potential confounding exposures to things like benzene that we need to address. We're also looking at the potential to evaluate plutonium dose to the bone marrow for workers, particularly at Oak Ridge,

10

11

12

13

14

19

16

17

18

19

20

21

Savannah River site, Hanford and Los Alamos.

A fourth case-control study is a study of K-25 workers who have multiple myeloma. Again, this is a very large study, one of the largest of its kind, and it follows Steve Wing and colleagues in their investigation of multiple myeloma across the DOE complex, and hopes to explore further some of the important exposures, particularly to internally-deposited uranium and multiple myeloma risk.

Lastly we have a multi-site lung cancer case-control study that is right now pretty much on hold because of all the other higher priority studies that had been currently underway. We don't yet have a health physicist assigned to this project, but Sharon Silver and Dennis Zaebst are working on this from an epidemiologic and industrial hygiene perspective. This study is also quite complex in that it's studying a number of different facilities across the complex, and it's attempting to get around the issue of confounding by other exposures like asbestos by restricting itself to workers in the reactor areas, and it's hoped that the exposure assessment for that group of workers would

be simplified.

10

11

12

13

14

19

16

17

18

19

20

21

22

Now I didn't mention it in each case, but as Dave mentioned, virtually all of these studies have to take into account not only the radiation exposures, but also exposures to other factors that could be either confounders that somehow are obscuring the relationship between radiation risk and cancer, or they could be effect modifiers, in which they're changing somehow. Different levels of exposure to those factors change your sensitivity to radiation or change the risk of actually getting cancer. And so in many of these studies, we're looking not only at evidence of confounding, but also for effect modification or interaction, which I'd like you to have a grasp on because it really is the heart of many of the questions -- the complex questions that this Board has asked and will continue to ask, in our opinion.

I also wanted to mention a few other key projects that are really instrumental in telling us where we're going to be heading in the future. The first -- well, really the sole one on this slide is the systems which we call HEDS, which stands for the HERB Epidemiological Data

management System. It's a complex database of

Department of Energy and Department of Defense workers,

all of which have been studied by HERB in some way or

another.

This study is linked by -- well, it contains demographic and work history data for Department of Energy workers. It also contains radiological exposure data, as well as non-radiological exposure data such as chemical exposures, physical hazards other than radiation. It could contain noise exposure or anything that we measure that isn't related to radiation. The data, very importantly, are linked by something we call a master roster, and every time we put a new cohort into HEDS, we have to match it against everyone else that's already in there so that we can find workers who went from facility to facility. And this linkage is what allows us to do multi-site studies and to carefully take into account exposures that occurred across the complex, because we do know that workers did move from site to site.

10

11

12

13

14

15

16

17

18

19

20

21

22

The key staff on this project are clearly our IT specialists, but we do have input as well from

epidemiologists, exposure assessors and others.

I wanted to touch briefly on some of our high priority future research projects. These include -- and really are based in some degree on our success in putting together the HEDS system. We would like to be able to conduct more multi-site studies because we really believe that they allow us sufficient power to overcome the problem we have in doing these low-dose chronic radiation epidemiology studies.

Some of the cohort-based studies we've considered are, for example, studies of the neutron-exposed workers across the complex. As I learned several years ago in sitting on a panel that IARC put together that was evaluating risks of exposure to gamma and neutron radiation, there really are no cohort -- human cohort studies of neutron exposures and risks directly from neutrons. We do believe that the DOE work force offers an opportunity to evaluate neutron risks directly instead of relying on animal studies or on studies of chromosomal aberrations or other lab-based studies.

We're also very interested in studying plutonium as a hazard across the DOE complex. We've -- I've told you

about a number of studies that involve plutonium exposures, and the most effective way we believe to study them is to combine them through our epidemiologic database system and to be able to evaluate, complexwide, the hazards faced -- or brought by plutonium exposures.

A few of the other exposures that have received slightly lesser priority, just because of the primacy given to plutonium and neutron, are perhaps uranium-exposed workers. A number of researchers -- and you'll see discussions of this in your briefing packet -- have looked across the complex at uranium exposures, and we believe the exposure assessments could be improved in that assessment and would like the opportunity to study that. We've also discussed conducting tritium and polonium exposure-based cohort studies.

As you may have noticed as you've gone through the briefing book, most of our studies are studies of cancer mortality, simply because those -- mortality data systems are well established for epidemiologic research and we know how to use them on a national basis. However, we do understand that these are not as

efficient for studying cancer incidence for disease that have low mortality rates, like skin cancer, prostate cancer or breast cancer. Now this is not to say that these aren't serious, deadly diseases, but compared to other cancers, it's -- you tend to see fewer of them if you only study mortality, and we believe it is important to study cancer incidence for these types of diseases. The problem, though, is that the U.S. doesn't have a good system for monitoring cancer incidence on a nationwide basis, and so it's difficult to find comparison statistics across a population. And it's even difficult to find incident cancer cases in a defined population, so we do view this as a high priority to develop and to evaluate such an incidence study system, but we're in the process of looking into that right now.

10

11

12

13

14

15

16

17

18

19

20

21

22

And for many reasons we believe that it's important to start assessing the information that we already have about occupational cohorts with respect to radiation exposure. One way to do this, if we can't combine cohorts using the raw data that's in our system, we would have to use information from studies that are

published in the literature. This is a common thing to do epidemiologically, and it's a way that epidemiologists can make sense of data from studies that give you conflicting information. It's a formalized research process called meta-analysis, and it allows you to incorporate results of studies when perhaps all you may have is the study design information, information about the risks and confidence intervals about them. And we believe that it is possible to begin doing these types of analysis, given the information we already have about DOE cohorts and that which we're about to get from these studies that I've mentioned recently.

Lastly, and very importantly, we believe that current worker exposures and health effects are of great interest from a public health standpoint. We have primarily been studying workers who were formerly involved in DOE production -- the era of DOE production. As you know, most DOE facilities have moved into a decommissioning and decontamination era, and we believe that studies of hazards of health effects faced by these workers is a very important

direction for us in the future.

10

11

12

13

14

19

16

17

18

19

20

21

22

Now I'd like to turn to what we learned from reading transcripts. Unfortunately, none of us were attending your February meeting, but due to the excellent minutetaking, we were able to understand what you discussed and agreed on as priorities in terms of research needs. And these are in no particular order. Russ Henshaw really helped us try to distill your discussion into a couple of different priority levels. The first I called level one and the second level two. The first is the incorporation of occupational studies into risk models, which you expressed as a level one priority. The smoking adjustment for lung cancer, which we've already heard discussed over the last day, was expressed as well as a level one concern or research priority. The incorporation of background cancer risks into the risk models was identified as a high priority item, as well as the grouping of rare types of cancer and prostate cancer, which isn't necessarily a rare cancer, but which -- of which little is known about risks from radiation exposures. Some of the lesser priority levels -- items were age at

exposure issues and the interaction of radiation with other workplace exposures. Now I don't know if this reflects your current thinking. This is what we were able to glean from, again, what we read from the February meeting.

So I'd like to go through, if I have time, our current research agenda and how we believe that it addresses several of your most important priority areas, as well as a few others that we thought of ourselves or that we learned through discussions with many of you in other settings.

First is the incorporation of occupational studies into risk models. And to us, this is a simple thing to say, but when you try to identify how a study fits into it, you really need to break it apart into its component parts. Because as you know, IREP itself is very complicated and doesn't have just a single model that's used to evaluate risk.

The first issue that we felt really touched on one of the major concerns is that we feel it's important to establish -- just as the atomic bomb survivor data is considered a gold standard of exposures that occur instantaneously, we believe it's important to establish an occupational gold standard against which risk coefficients could be based and evaluated.

Because of the different flavors of radiation and the

different effects that they may have on tissue and on cancer risk, it's simplest to break this up into exposure types. So starting with high energy photon exposures, we have several studies that have either been completed or are soon to be completed that are looking primarily at high energy photon exposures and don't have a lot of other exposures that make the picture much more complex. These include the cohort mortality study of Portsmouth Naval Shipyard workers, the study of INEEL workers, the cohort mortality study — we believe the best study of that will be the most current study since it takes into account more recent cancer mortality. And this, as I said, is a grant that we expect to be completed sometime this summer.

The new grant that we've just funded with Dr.

Richardson to look at cohort mortality among Savannah
River site workers we believe will also answer some key
questions with respect to high energy photon exposures.

And yet it's important to remember that each of these studies could give us very different estimates of risk on an individual basis. This is why we believe the combined cohort studies that allow you to not just pool results from a risk estimate basis, but also combine the basic data that's used to derive risk coefficients could be very important.

As Dave mentioned, though, there are many researchers who are also doing important research on this area. For example, studies of X-ray technologists that are being conducted by the National Cancer Institute are also occupationally-based and also are concerned with relatively low, chronically-received doses. not instantaneous high-dose exposures. So it's unlikely that we'll get raw data with which to pool DOE However, we could conduct meta-analyses that data. incorporate not just DOE and DOD cohorts, but also other occupational cohorts that could give us very valuable information on higher energy photon risks. Another obvious one is the study of cancer among the international nuclear workers, which is one of the largest studies ever to be conducted I think of

10

11

12

13

14

19

16

17

18

19

20

21

anything epidemiologically. It has over half a million people in it.

A second question that we feel is extremely important is not only to look at high energy photons as a gold standard, but to directly assess the risks of exposures to internal emitters and to neutrons. As I've mentioned, several of our studies, including the Rocky Flats cohort study as well as the Rocky Flats lung cancer case-control study, the Fernald lung cancer study looking at radon exposures, the Savannah River cohort mortality study which is looking not only at photons but at tritium exposures, the study of multiple myeloma among K-25 workers, neutron-exposed cohort study which has yet to begin, and again combined cohort studies like the plutonium, uranium workers and other studies based on radionuclide exposures. Again, we also need to consider incorporating, through hopefully meta-analysis or some other technique, data from non-DOE cohorts such as Mayak worker studies, although the dose ranges for that study are far greater than most DOE workers have experienced, so the relevance is not quite as good as it is studying this in the population

10

11

12

13

14

19

16

17

18

19

20

21

of DOE workers themselves.

10

11

12

13

14

19

16

17

18

19

20

21

22

We've identified a few other issues related to exposure assessment, and you may ask why this is being considered in the HERB setting rather than in the dose reconstruction setting of OCAS. We also think it's very important in producing accurate risk estimates to work with the best exposure data possible. And to do this, we need to address key errors that may exist in dosimetry in conducting our epidemiologic studies. One of these is the direct assessment of organ doses from internal radiation exposures. As we know, commissions like the ICRP and other international and national bodies continually update and improve their dose assessment models, and we would like to be able to incorporate these as much as possible into our epidemiologic studies. We're doing this in a grant setting through the Rocky Flats lung dose assessment project. We're also looking, as I mentioned, at plutonium bone marrow doses in the multi-site leukemia study, which could help us address the issue of RBE in leukemia for alpha emitters. As you saw, that is a key question that still remains in the IREP program.

The multiple myeloma K-25 case-control study is looking at direct organ doses to uranium -- enriched uranium exposures. And we're also looking at radon and -- lung doses to radon in the Fernald cohort mortality study and in the lung cancer case-control study being conducted by our grantees.

In addition to internal emitters, we're also concerned about organ dose characterization for neutron exposures, and so as we move into the phase of studying neutron work-- exposed cohorts across the complex, a very important aspect of that is the exposure assessment and neutron dose assessment. As Dr. Kocher's presentation explained yesterday, there are still key questions about transferring organ doses from animal studies into human studies, and that is a question that we're very concerned about, as well. Oh, I skipped one, which is the additional sources of uncertainty in the dosimetry in epidemiologic studies. This is a well-studied phenomenon that continues to advance as researchers prove their uncertainty analysis techniques and dosimetry analysis techniques. Several of our studies are well-suited to study these

10

11

12

13

14

19

16

17

18

19

20

21

particular issues, particularly the Portsmouth Naval Shipyard cohort studies.

A second priority that received some discussion yesterday was the issue of a smoking adjustment for lung cancer. And as epidemiologists, the way that I like to view this is in a question that can be either confirmed or refuted. One of these is exactly what is the interaction between smoking and radiation exposures, for not only lung cancer, but for other cancers as well. As poor as the data may be for lung cancer, it's far better than for any other smoking-related cancer, and there are many of them. We just don't have a lot of information epidemiologically about how smoking interacts with other exposures, including radiation.

The Rocky Flats lung cancer case-control study, as I mentioned, is specifically evaluating this and I'd urge you to read that report if you're interested in this topic. Several of the studies that we have underway that address -- directly address this in nuclear workers is the Fernald lung cancer study, the Portsmouth Naval Shipyard lung cancer case-control

study, our multi-site lung cancer case-control study, our multi-site leukemia case-control study -- which is an example of another disease in addition to lung cancer, and we believe it's important to conduct a careful structured review of these and other studies that have been conducted looking at this issue in the past.

This is -- does pose a great challenge in DOE cohorts, however, because most of our studies, as you see, are case-control studies in which the case has already died. And so in some cases it is difficult to get smoking information. We've made great use of medical records within the DOE complex in order to obtain smoking information that's unbiased because it was collected in advance of the person becoming a lung cancer case or entering into our study.

The issue of incorporation of background cancer risks we split into two different topic areas. One is the use of adjustments for racial, ethnic and other group differences, and also temporal changes, changes over time. As you know, the IREP model is based on background rates that are fixed at one point in time.

However, cancer rates have changed over time and in some cases increased, in some decreased. Workers who may be claimants could have become sick many, many years ago, and the issue of which rate one uses to adjust for background risk is of some interest.

Now this isn't necessarily a research question for HERB. However, we do believe that the use of direct risk estimates from DOE worker populations would to some degree obviate the need to use a risk transfer function in the IREP models, which we believe to be of great importance in -- to this Board.

A second question is the use of adjustments for radiosensitive subpopulations. Now it's been a while since I read the actual enabling legislation for the program, but I think I recall something about looking into radiosensitive subpopulations. That's something that doesn't currently exist in the IREP modeling. However, we are interested in looking at risks by gender, by race if we have sufficient numbers, and perhaps other factors. And some of the other studies that are already looking into this are listed here. This is something that we note is of great interest

across the entire scientific community and is something that may grow in interest and importance in the coming years.

You identified another fairly high priority item which is how the different rare cancer types are grouped, and issues about prostate cancer. We view this as looking into developing risk models for some of the more rare cancer sites, or for cancer sites for which the radiation risks are not well known, such as prostate.

Now breast cancer is well known; however, one -- male breast is of concern. However, very few studies have evaluated breast cancer risk in men and what the risk factors are for that.

In order to address some of these -- we do have some proposed studies. As I mentioned, it is difficult to do incidence studies in the DOE work force and really in any large U.S. population that's mobile, like the DOE work force is. However, we've evaluated conducting a skin cancer incidence study, a prostate cancer incidence study. We also believe that evaluating some of the rare cancers could be more feasible if we use a combined cohort approach that combines data from many

facilities in order to increase the statistical power to evaluate risk. Again, a meta-analysis or structured review of not only HERB studies but of other occupationally-exposed cohorts could help us address this issue.

The issue of age at exposure is one that we've been keenly interested in, as has the Board. This, we feel, breaks into two different questions. One is how does radiation risk depend on the age at which a person receives exposure.

The other is really an epidemiologic problem, which is that it's very difficult to study complex exposures that occurred continuously over time because there are so many factors that could weigh into what the risks are from. One of these is age at exposure. As we heard from Owen, the issue of attained age, how old one is when one gets cancer, is an important potential risk factor. The duration of time that occurs between when exposure occurred and when disease might occur is another factor. All three of these are very difficult to study independently. And depending on how one chooses a model, you could get very different results

about age at exposure if you look at these other factors in -- concurrently or separately. So it is epidemiologically a very -- that's, in my opinion, why it's so difficult to get a firm answer on this, is that there are so many other factors that are co-occurring along with age at exposure.

As I mentioned, we have a contract and several grants that are looking specifically at age at exposure issues. The Rocky Flats lung cancer case-control study did evaluate age at exposure, as well as several cohorts, including Hanford, Savannah River site. I believe the PNS cohort mortality study can address this to some degree, as well as the Idaho cohort. The International Nuclear Workers study is looking into age at exposure, as well, combined across a large group of workers. And again, to increase the statistical power to detect small differences or changes that are affecting other risks, as well, we believe the combined cohort analysis and perhaps meta-analysis is a good way to approach this problem.

The interaction of radiation and other workplace exposures was identified as an issue of some importance

to this group, and as you know, IREP assumes that the interaction is multiplicative. That is, it doesn't matter what your other exposures were, your risk from radiation is the same whether you were exposed to no other chemical -- or no chemical exposures, a moderate level of chemical exposure or a very high level of chemical exposure. The relative increase in your risk, which is what directly affects your probability of causation, is the determining factor. And that's assumed to be equal across categories.

So the question then boils down to is there evidence for a departure from a multiplicative interaction, and if so, which direction does it go. In some cases that change could be less favorable to the claimant, and in some cases more.

As Dave indicated, several of our studies do address mixed exposures. However, no study addresses all kinds of mixed exposures. It would just be too difficult to study and probably not possible, given the range of activities that occurred across the complex. However, some of the studies that I've already mentioned are looking at interactions with chemical exposures, with

benzene and carbon tetrachloride in the case of leukemia risk, with asbestos and welding fume exposures in the case of lung cancer, with -- let's see, uranium with external exposures, including work-related X-rays and chemical exposures in the multiple myeloma study, and on and on. We really -- every study has to consider how the radiation exposure interacts with other co-occurring workplace exposures.

Some other issues that weren't raised at your February meeting but which I recall being raised in the past and which certainly have come up already at this meeting are important, in our opinion, and we have studies that will be addressing these issues. A couple of these are risk models for radiation exposures in chronic lymphocytic leukemia. Although the Department of Labor is returning letters that say there is zero probability of causation, the scientific evidence for that is not that strong. And many of our studies are addressing CLL risks directly. These include the multi-site leukemia case-control study, the PNS leukemia study, and we believe we're seeing enough leukemias in other cohorts as well that some combined

investigations of -- across the DOE complex could address this. CLL, as you know, is rare in the Japanese population. However, it is fairly common in western populations. And so not only are DOE studies important, but meta-analysis or structured review of additional western populations like the Canadian workers, the British workers and several others will be of some importance. And I should add that the IARC study will also be looking into risk of exposure for CLL, as well.

The adjustments for latency for radiogenic leukemia we know you addressed in an administrative setting or policy setting in your last meeting. However, there are still important scientific issues related to this.

The time period that elapsed between the exposure that

occurred in Japan, the atomic bomb blasts, and the initiation of the studies is such that they can't answer that question using the Japanese data. It's really incumbent on other research studies to look into this issue. The standard thinking is that two years is sort of the standard latency adjustment one applies for leukemia risks. However, that has not been empirically

determined to be the best or the most accurate latency.

And so several of our leukemia studies are looking
into this issue, as well.

Two more issues are the direct evidence for a dose and dose rate adjustment factor that occurs in occupational Now that -- you've mentioned some potential studies. adjustments that could occur from IREP, but this really is a central topic of great concern in conducting any occupational cohort study because it's inherent in the design of the study that we're dealing with populations that are exposed at a lower dose rate to lower levels. And so any -- generally any study that evaluates risks compares the findings for risk coefficients for a low dose rate, low dose exposure to studies like the Japanese atomic bomb survivor study. And those kinds of comparisons have been done in the past and will continue to be done. We think that there really needs to be a careful look at this, not only in a combined study basis, but reviewing what other studies have found to address this issue to help us, using the existing human data, to answer the question, without relying on either theory or animal studies.

10

11

12

13

14

19

16

17

18

19

20

21

22

And lastly there is a minor issue related to the cut points that the NCI program uses to determine what an acute dose is versus a chronic dose. I don't know how or if this is really applied in IREP, but it is something that piqued our interests as researchers and we believe we can attempt to evaluate this, to some degree.

I wanted to leave you with a few issues regarding current workers. As Dave mentioned, public health issues related to current workers and the health hazards that they face are of great interest to us because we know that problems didn't end with the end of the production era. A few of the issues that we have identified and that have been outlined in some of our documents that you'll see in the annotated bibliography include the fact that D and D era workers could face not only different hazards in the workplace, but also health effects that could differ from those of concern to current workers. And we have been in contact -- Travis Kubale in particular has been in -- done an outstanding job of reaching out to current workers to try to identify issues of concern to them.

And we are gathering this information to help us develop future research and other activities that could help address the hazards and health effects of concern to these workers.

One of our very important findings is that for these current workers the -- well, we're hearing concerns right now about the adequacy of radiation monitoring and health monitoring, even in current workers, particularly in subcontractors who may have -- not have access to the same level of monitoring as prime contractors at a facility.

And lastly, we've identified the fact that information quality that could support future epidemiologic studies and also compensation practice is of some concern to us, and we've identified this in a document published a couple of years ago. We hope that DOE will be helpful in responding to these concerns, but we do feel that the documentation that could support future studies is of great concern and something we're hoping to address. For further information about this you can reach us via many mechanisms. Talk to us here, call us at this number. We have an excellent web site that contains

full reports of many of the things that you've seen annotated in the listing.

We also encourage you to, if you'd like us to come back and talk to you, we'd be happy to do so at some point in the future. And with that, I'll open it up for questions.

DR. ZIEMER: Thank you very much, both of you, and -- I get a little amused at all the acronyms, particularly when acronyms include other acronyms as part -- but I am looking for the day when every letter of an acronym is another one. But -- and we use that to shorten things, so I'm going to call you Dr. MS-B. Dr. MS-B -- DR. SCHUBAUER-BERIGAN: That's fine.

DR. ZIEMER: -- would you identify for our group -- I know you have a number of your colleagues from the group from HERB here today. Could you identify for the Board the other HERB individuals? I've met some of them but not everybody has.

DR. SCHUBAUER-BERIGAN: Sure, I'd be happy to do so.

Perhaps they'd be willing to stand as I say their name.

The assistant branch chief, Dr. Steven Ehrenholtz* is with us and he's been in HERB for quite a long time and

I'm sure is familiar to many of you. Next to him we have Dr. James Yiin, who is an epidemiologist who's fairly new to our branch and who's got expertise in statistical analysis of epidemiologic studies and in risk assessment, as well. Travis Kubale, who is not only our help communicator and a doctoral student, but a tremendous outreach asset to our group, as well. Scott Hind* who is at the end is a contractor with us. He's an industrial hygienist and he's helping us to get these studies done and get them out the door. Dr. Greg Macievic, who I almost missed here, is a health physicist who's been with us about a year and a half now, who is conducting -- health physicists are in very short supply in our group so we spread them rather thin across the projects. He's on three of our very important cohort case-control studies. Did I miss anyone? Okay.

10

11

12

13

14

19

16

17

18

19

20

21

22

DR. ZIEMER: Thank you very much. I suspect there are a number of questions and I would like to ask you to do two other things before we get into general questions.

Early in your presentation I think you -- maybe it was Dr. Utterback -- mentioned analytical epidemiological

studies, and would you define for the Board and for the public the difference between analytical epidemiological studies and descriptive epidemiological studies? This is a test. Maybe we should ask the PhD. candidate to do this.

DR. SCHUBAUER-BERIGAN: He's hiding and he's shaking and -- no, I'd be happy to do that. It's a very important question, and it is raised frequently. A descriptive epidemiological study is one that attempts to define disease in terms of where it occurs, when it occurs. It's really defining its occurrence in time and place and among people -- who is getting the disease, what are the rates of disease. It also includes studies that are not necessarily done on an individual basis. And in the radiation community you frequently see published things like what we call ecologic studies that are conducted at the level of a population rather than at the level of an individual person. And so you might see someone comparing rates of cancer in India in a low altitude environment where radiation doses are low with people in Colorado who might get higher doses and look at cancer.

10

11

12

13

14

19

16

17

18

19

20

21

22

considered non-analytic because it doesn't take into account what's happening on a personal level.

In contrast, an analytic epidemiology study looks at the level of the individual and it also tries to evaluate associations between disease and some kind of exposure, in this case radiation exposure. And the most common designs are cohort studies, case-control studies and the like, and that's -- that is what we conduct.

DR. ZIEMER: And then one other item that was mentioned, sort of in passing, but -- and might have escaped notice was the use of CEDR, and would you describe for the Board and for the public the Comprehensive Epidemiological Data Resource?

DR. SCHUBAUER-BERIGAN: Surely. You've already defined the acronym and for the record, again, it's the Comprehensive Epidemiological Data Resource. It operates by the DOE. They are the keepers of CEDR, and they've contracted with -- is it Lawrence Livermoor?

UNIDENTIFIED: Lawrence Berkeley.

DR. SCHUBAUER-BERIGAN: -- Lawrence Berkeley Laboratory to actually operate CEDR on their own storage systems.

CEDR contains de-identified information containing analytic files that were used to conduct epidemiologic studies. So as you go through the annotated bibliography and see a study listed in there, if it's been completed and it has been conducted among DOE workers, the Department of Energy wants the de-identified data from that study, including mortality or incidence information, any other extraneous factors that were used to conduct the study, and also exposure assessment information in the files of CEDR. And any qualified researcher who would like to have access to the data to study it is eligible to apply and to receive permission to use the data.

DR. ZIEMER: Thank you. Dr. DeHart has a question.

DR. DEHART: Currently there are a number of clinical evaluations that are ongoing with non-DOE workers who were contractor workers at some point in time at DOE facilities. For example, construction workers, an organization that's working with them, a union-supported research activity there. What kind of interface is going on between you and those -- that clinical data?

DR. UTTERBACK: Just to clarify, I believe you're referring to what collectively at DOE is known as the former worker program of providing medical screening for workers at Department of Energy sites, and there are a number of these that have been underway. I think the number right now is 15, maybe 16 of these programs, and some sites have multiple activities.

We do interact with this group. We try to keep abreast of changes that are going on with that group of investigators and clinicians, and we are trying to work with the Department of Energy in evaluating the value of that information for protecting worker health, not just site by site, but collectively across the sites. So very recently, just this spring, we were able to get copies of the questionnaires that are administered to these workers as they are introduced into the programs to try to determine what kind of information is collected, how consistent it is across the site and what the capabilities may be of collapsing the data —that's a term that we use for kind of bringing everything together. And just this past week we did get a report from our investigator, Dave Peterson, and

a contractor that he's working with, Phil Beirbaum*, in analyzing the content of the questionnaires. And of course any time you go through that sort of a process of trying to look across a variety of different information sources, you know, the first result that comes out of that is a whole list of additional questions that you now have. So we are -- we want to try to work with the program, try to evaluate the value of that information for protecting not only former workers, but also current workers and some of the individual investigators. I know Mark Griffon's involved in a program, as well. You are looking at this, you know, within a site, trying to identify where hazards that maybe were not recognized by the current staff who, you know, people go to for information about historical exposures are trying to utilize this information they're getting from the workers, you know, from the sites and trying to identify where hazards may have exist over the lifetime of the facility. So we believe that potentially it's a very useful set of data.

10

11

12

13

14

19

16

17

18

19

20

21

22

Unfortunately, just like, you know, data systems vary

from site to site. If you look at Los Alamos versus Hanford, you know, run by two different contractors, they've got different data systems, different organizations, different ways of running things. The same occurred with these former worker medical screening programs. Each site basically developed their own data systems, their own set of questionnaires and the like, and so it will be challenge to try to bring that information together and try to analyze it appropriately.

Thank you for the question. I think it is a very valuable -- potentially very valuable resource.

DR. ZIEMER: Let me ask a question regarding plutonium workers. In that -- in those studies do you have access or do you use any of the database from the U.S. Transuranic Registry in the...

DR. UTTERBACK: The work with plutonium workers that was recently completed with, you know, Jim Ruttenber at the University of Colorado Health Sciences Center and the Colorado Department of Public Health and Environment is -- well, as a matter of fact, I think one of Owen's colleagues that was here yesterday is

working with that group and trying to develop a model for doing lung dose estimates for the lung cancer cases and controls within that study. And then they want to compare — this is based on a conversation I had with Dr. Ruttenber last month, that they want to compare their predicted lung doses with what they are getting from autopsy tissues — or from the tissue samples that come from plutonium—exposed workers that are maintained by the Transuranic Registry. So I mean we have not used any of that information directly within our studies, but the link is going on, you know, through an external investigator.

DR. ZIEMER: I'd also like to ask about Chernobyl workers, such as the liquidators. Are there any -- do you have any collaborations going on? I notice you're looking at Russia and the Mayak people. What about the Ukraine and any of the Chernobyl-related workers?

DR. UTTERBACK: Once again, we have an extramural grant that is addressing that issue. It is by Dr. Elizabeth Cardis at the International Agency for Research on Cancer, IARC, in Lyon, France. And she's doing the dose reconstruction for the Chernobyl liquidators, as

they're called. It's a very large population of workers who responded to the incident and over the succeeding months had relatively -- well, very high doses of both external -- and many of them had internal exposures, as well. And we do anticipate a report on that study within the next six to 12 months, I would add.

DR. ZIEMER: Leon?

MR. OWENS: In regard to the study that was initiated at Paducah by the University of Kentucky and University of Louisville, I know that study got off to a very good start. There appeared to be -- have been some setbacks. Do you have an expected date on when that study will be completed?

DR. SCHUBAUER-BERIGAN: I have not recently seen a projected end date, you know, for that study. They are preparing right now for a site visit to begin the collection of the records necessary to complete the study. This is a study that involves University of Louisville, University of Kentucky, as well as some of the staff at the University of Cincinnati who will be involved in getting that work done. And they are

preparing, I believe within the next couple of months, you know, to get to the site and begin to collect the records and -- you know, initiating a cohort study like this, they're doing a study of a group of workers that's never been studied before. It's a large undertaking. We've learned this lesson the hard way, you know, doing a Denovo* cohort analysis on a working population is a huge undertaking. The INEEL study is one that we began early on in our group and we are just now wrapping it up, you know, some ten years later. That's a very large cohort. We're hoping that the Paducah worker cohort is going to be -- you know, given it's a much smaller work force, Idaho is a national lab, have people moving in and out a lot. Hopefully the work force at Paducah is more stable.

MR. OWENS: We were -- we were concerned because the union was directly involved in the initial meeting that was held at Paducah. We had a small group of former and current workers who were assembled together to assist in the information collection, and since that date -- which has been about six or seven months ago -- we just haven't had any additional follow-up, so that's

why I wanted to at least find out the status.

DR. UTTERBACK: Well, I know they are working through some of the business aspects of, you know, getting contractors in there so that they can collect the information, and that's the most recent activity that I've seen there. They're just trying to get those things worked out.

You know, there is a process of getting access to these sites that oftentimes is -- is problematic. I mean you wind up investing a lot of time in finding out what the rules are, what the limitations are on access to various things you want to look at, and then trying to put together some sort of a solution for addressing that particular problem at that site. So I -- you know, I'm very optimistic -- an eternal optimist -- and I'm very hopeful that they're going to be in there very, very shortly and begin to collect the records. And some of those are electronic. Some of them are microfilm, microfiche and some of them are paper, and that can be a very difficult problem.

One of the problems there is that there's pertinent records to that study that are in the vault, and the

vault is a secure area because it also contains, you know, information that's restricted for national security reasons. So getting people in there requires people who are cleared, and getting a clearance is something that takes time, especially these days. Thank you for your question, though.

MR. GRIFFON: Yeah, I was just looking in the attachments and -- that you provided on summaries of all the studies, current and past. And I was -- I was thinking that it might be a valuable tool -- going on the discussion we had yesterday, it might be a valuable tool to take the matrix that you developed, Mary, showing the items of interest to the Board and lining up current studies that might be also useful to integrate the past studies of relevance for those certain factors, like the gold standard photon studies, and group them by historical -- that might be a starting point for us to look at how we might use some of those past studies to modify uncertainty estimates in the IREP model or something -- you know, at least initiate discussions on that topic. I know, you know, we have questions of how quickly or when we can do

10

11

12

13

14

19

16

17

18

19

20

21

22

that, but -- is that something that can possibly be provided?

DR. UTTERBACK: Well, I mean I really kind of see that as an initial step in pursuing some of the research goals that we talked about, trying to figure out, you know, what is there and where it fits into this kind of matrix of -- of questions and issues that have been, you know, brought to our attention by the Board and by the people working with the Board. It really is an analytical process to do that. It's not a matter of just well, they did external exposures here and they did external exposures there, because it's never clear cut, and you have to be very careful about beginning to sort these things out. But I do believe that it's a very worthwhile analytical process, and I do believe that the stage that we're at now with the occupational studies presents this opportunity to us finally, that we are getting cohort analyses done on these very large populations in such a way -- and we've worked very hard over the years to try to do these studies in such a way -- that they can be combined for future analysis. it's not -- as Mary pointed out -- you know, based on

10

11

12

13

14

19

16

17

18

19

20

21

22

exposures, but also on the cohorts and looking at, you know, some of the larger questions of external -- the effects of external radiation, you know, particularly gamma radiation in these occupational cohorts. You know, it's something that we are looking at addressing in the future. You know, it's something that would require some change in the strategies and the way that we've done studies in the past.

And frankly, you know, it's going to be easiest to do if we are able to identify, you know, additional resources to make that possible, not only, you know, financial resources, but also the intellectual resources, the people, you know, the most important part of our program. We need to find the people that have skills in this area that can bring them to bear in the most efficient way. If we have to retrain, retool our people, then that, you know, stretches out the timeline a little bit.

Yeah, we believe that the stage is set and we'd like very much to -- you know, to pursue that line of reasoning within these studies.

DR. ZIEMER: I'd like to ask a question that, in a

sense, cuts across many of these studies and to parallel this question with what's done on individual dose reconstructions. In your studies of various sorts, whether they're case-control or otherwise, somebody is having to take some dose data -- DOE dose Now in our case, there's a lot of massaging data. done. We take the dosimetry data, there's some corrections made for missing dose, there's corrections made for certain medical exposures that were required as part of the job and -- you're all aware of this -and there's a distribution that's associated with that, not just a point value. Now I'm trying to get a feel -- we have a number of investigators doing these other studies, these analytical epidemiological studies, and I'd like to get a feel for to what extent is there a somewhat common protocol in establishing what the dose values -- 'cause obviously you have -- you're looking at dose versus effect in a population type of situation. Can you talk a little bit about the uncertainties in those that are used there -- I think in many studies they bin these doses; they take groups of people that have doses between some lower and upper

10

11

12

13

14

19

16

17

18

19

20

21

22

value and there's a variety of bins. Right? But give us a feel for what's required -- how -- how the investigators are using the DOE dose data, which everyone is saying is inadequate, and if it's inadequate, what are they -- and we do things to make it adequate for compensation decisions. How are the epidemiologists making it adequate for their studies so that we have confidence that the final result is useful, even for our use?

DR. UTTERBACK: I mean you -- you mentioned several things that are -- that are used, including, you know, utilizing dose ranges instead of individual values, you know, doing the categorical analysis instead of analyzing continuous variables. That -- you know, I -- that is -- is a -- I mean how much time do I have? I mean --

DR. ZIEMER: Well, I think --

DR. UTTERBACK: We could bring out some health
physicists --

DR. ZIEMER: I think if you could give us kind of an overview of how -- I don't want to get into all the detail here, but it seems to me, even if you're going

to do meta-analysis, you have to have some idea of whether the investigators are approaching this in a sort of somewhat similar way, or how do you put this all together?

DR. UTTERBACK: Actually --

DR. ZIEMER: And remember you're speaking to largely non-epidemiologists here.

DR. UTTERBACK: You know, we would like to come back and bring, you know -- we do have a health physicist here with us who could come up and talk a lot about this. We would like to come back and maybe address that at some point in the future, but all those things you mentioned are areas that over the past decade of conducting this research that we've discovered as being important issues. The role that medical exposures and, you know, occupationally-required medical evaluations and the X-rays that are associated with that and how that affects the dose estimate for the workers as missed dose is something that early on was recognized as an issue due to censoring within the data limits of detection on dosimetry, a variety of other things, and in some populations only portions of the populations

being monitored, and internal dosimetry presents this whole sundry of uncertainties as we go through this process. So you know, it is different because, you know, it's not sufficient within the epi study -- and I'll defer to Mary very shortly on this, but you know, to do the distribution of uncertainty and assign that to each individual worker. You know, instead we want to come up with some estimate of the central tendency, you know, what is the best estimate of exposure for this worker, and then, you know, run that through the analysis. So you know, these are all things that we work very, very hard on. We've got some very talented individuals and some very detail-oriented individuals who really dig into this and find out what the records will support, what is possible to do and what are the best estimates that we can derive.

10

11

12

13

14

19

16

17

18

19

20

21

22

DR. SCHUBAUER-BERIGAN: I would only add to that in a couple of sentences. One is that most -- or many epidemiologic studies, not just worker studies, put exposures into bins. The lung cancer study done by Dr. Pierce Owen Hoffman referred to yesterday is one such study of the Japanese survivors that did classify

workers according to the bin of radiation dose. It's of course imperative that you put workers into the proper bin in order to have an accurate study. And as Dr. Utterback indicated, there are many methods that we incorporate to try to do that.

We may end up not being able to entirely determine which is the best estimate. And in that case, we would frequently conduct what's known as a sensitivity analysis to use a range of possible alternative doses that could have been applied to that population and to determine how risk estimates might change. And that's part of the analysis one would have to do in order to incorporate different cohorts into a single analysis.

DR. ZIEMER: Thank you.

MR. GRIFFON: Yeah, you know, Paul's question triggered a question for me. Just -- just fro-- does the HERB branch have access to OCAS records? I imagine there's some privacy issues or -- or some -- but does the HERB branch have access to -- specifically, instead of the broader question, I was thinking of the case-control studies that you have ongoing where it might be very advantageous to look to some of the extensive health

physics work that's going on in the OCAS branch for particular cases that are in your case-control study -- or controls that are in your case-control study.

DR. SCHUBAUER-BERIGAN: I think at many levels there is a lot of interchange between HERB and the work that OCAS is doing. They've discovered a tremendous amount of information that's been very useful to the conduct of our epidemiologic studies. So far, to my knowledge, we haven't received any individual level exposure data that would contribute to our studies, but the data discoveries and data sources that OCAS has made to date have been very useful to us.

MR. GRIFFON: But do you intend on -- on looking for that data? I mean -- or would you do a parallel process where you would reconstruct your doses independently of OCAS or...

DR. SCHUBAUER-BERIGAN: It gets tricky in an epidemiologic setting because you end up, in some cases, having a different exposure assessment for your cases than you would for the non-cases because clearly every claimant -- the claimants who come in are most likely to be cases in our studies, and so that leads to

problems epidemiologically in doing analysis. But we would certainly take any higher level information that could be useful that would help us further refine our exposure estimates.

MR. ELLIOTT: Let me add to the first question that you asked. There's one system of records under the Privacy Act at NIOSH that -- that both the HERB research studies are added to the system of records which OCAS has access to, and we've utilized that information as best we can. And the information that OCAS receives from claimants and from our dose reconstruction effort, from our interviews, all of that is under the same Privacy Act system of records and HERB, in a institutional review board-approved protocol study, could have access to that if the study design called for it and was approved for that.

DR. ZIEMER: But of course keep in mind that many of the dose reconstruction values only go far enough to determine probability of causation, and then you can stop. So that may not be the dose. If you have enough dose to get compensated, this -- the analysis is carried no further. That's not the value you need for

an epi study, so there are two different endpoints that are of interest.

Again, thank you very much. We appreciate a very informative input to the Board on this topic.

DR. UTTERBACK: Thank you for having us here. It's been a pleasure. We always love talking about our research program and would welcome the opportunity to come back at any time.

DR. ZIEMER: And we appreciate meeting your colleagues, as well.

10

11

12

13

14

15

16

17

18

19

20

21

22

We're going to take a 15-minute break, and then we'll return for working -- Board working session.

(Whereupon, a recess was taken.)

BOARD DISCUSSION/WORKING SESSION

REVIEW PROCESS OF COMPLETED DOSE RECONSTRUCTIONS

DR. ZIEMER: I'm going to call the Board back to order.

We have a number of items to take care of yet, so if

you'll take your seats we'll proceed.

We're going to move now to a work session on dose reconstruction review process. I believe, Board members, you should now have some handouts from the dose reconstruction work group. There are I believe

three documents. One is called procedure for processing individual dose reconstruction reviews; one is task order, dose reconstruction procedure and methods review; and the third is task, individual dose reconstruction review.

Mark, is that correct? Those are the items?

MR. GRIFFON: Yeah, and then --

UNIDENTIFIED: (Off microphone) And then there are
some others.

MR. GRIFFON: Yeah, there's three more that I think are being cop-- oh, that are -- have been handed out.

Right? Three more from yesterday.

DR. ZIEMER: Okay. The other items, there's a copy of yesterday's slides and I see a copy of a summary review for a basic review and advanced review.

UNIDENTIFIED: Correct.

10

11

12

13

14

15

16

17

18

19

20

21

22

DR. ZIEMER: All right. So there are six documents.

Make sure you have those.

So let me -- let me turn this over to Mark -- Mark, if you would, what I'd like to do if we can do this is try to limit this to 30 minutes, because we have an additional item we want to discuss before the public

comment period.

10

11

12

13

14

15

16

17

18

19

20

21

22

Wait a minute. Are we behind schedule?

Okay. Well, yeah, try to limit this to --

MR. GRIFFON: I'll try -- I'll try to pick out the -- the big items.

DR. ZIEMER: Let's move ahead, yeah.

MR. GRIFFON: And let -- and -- yeah. What I -- what I can probably do is just tell you what we did as a working group last night and this morning. We -- we -the three document -- the first three documents that Paul mentioned to you here, the first one is a procedure -- a draft, I should say, procedure for processing individual dose reconstruction reviews, and then the other two are separate tasks -- draft tasks that we sort of extracted from the task order contract itself. A lot of the language in the two tasks you'll recognize. I -- we did do some additions to those, but a lot of it's similar -- you know, sort of cut and pasted from the original task order contract. And I think what -- the process here, I think the -that -- that I think might be appropriate is we -- we would like -- we would like these certainly available

when the contract is awarded, some of this stuff to be all in place. And the notion was to get some drafts out today, as rough as they may be, and then by the time we have our next Board meeting we would -- we would get full comments from all Board members and draft a final document at that point.

So, you know, I think -- 'cause there's a lot just to throw on you for a 30-minute discussion to review and give all comments, so I think the real intent is to take these back with you and have more -- a full discussion and -- and come up with a final draft at the next meeting.

Having said that, I should point out some things in the -- in -- I'll start with the procedure and processing the individual dose reconstruction reviews 'cause I think it builds on some of the points from my overheads yesterday, some of the discussion items that I -- I threw out at the end of that presentation yesterday. You can see there are several parts of this -- selections of the cases for review -- I don't know, are copies available for the public? I see -- okay. All right. Selection of the cases for review, designation

of Board members to the individual dose reconstruction case review. Section B there, we made some assumptions in this draft about how many cases would be done, and that was from the original -- the original task order contract, and then I -- you know, we made a estimate here that we would -- we would do 25 cases every two months, just to sort of give us something to think about in terms of how are these things going to be processed and what is the burden going to be on the contractor, as well as on the Board members that are going to be involved. I note that Board members, on a voluntary, rotating basis -- I -- I think that a lot of people -- a lot of individuals on the Board are -- are interested in participating in this, but I think everybody wants a little better definition of what participate means, what -- you know, what extent each individual Board member will have to be involved in this. So it would be -- you know, 25 cases every two months, cycling through at least for the initial year, based on the estimate of cases we did in the task order contract.

10

11

12

13

14

19

16

17

18

19

20

21

22

The distribution of data -- this question -- Section C

is the distribution of data to the contractor and designated Board members. I note in here something that -- that I think we need -- as a discussion, something that came up in the discussion items yesterday, which is -- NIOSH will provide data -- all data related to the individual case, which -- parentheses, the entire administrative record -- to both the contractor and designated Board members. And I've had some discussions with Larry on -- on just, you know, whether this can be done, given Privacy Act concerns, and I think we might want to ask NIOSH if there's any more word on that -- where we stand on that. I guess we should do it as we go, as...

DR. ZIEMER: Yeah, I don't know that we need the

MR. GRIFFON: Just to point out --

answers to all of these necessarily --

DR. ZIEMER: -- today if they don't have it, but at least they need to explore that and -- and while I have the mike, let me suggest that everybody on the Board and those members of the public, as well, just mark all of these copies as draft -- all this whole packet of stuff -- none of this has been approved by the Board.

These are working drafts, so I think it would be appropriate to label them as such, and that way you will not later mistakenly think that these are procedures as they will be used 'cause they're subject to change.

Additional comment, Tony?

DR. ANDRADE: A quick question. Mark, item number one on C, just so that I can go home and think about it correctly, it says case numbers will be provided to NIOSH. Who is supposed to provide these case numbers?

MR. GRIFFON: Right, in the -- Section A, the idea is that the Board is -- is going to do the random selection of the case numbers --

DR. ANDRADE: Okay.

MR. GRIFFON: -- based on a random stratified approach, and then we give those numbers for them to pull the records -- the language might not have been great there, but that's the idea, yeah.

DR. ANDRADE: That's fine. Okay.

MR. ELLIOTT: Let me speak to the Privacy Act question.

I don't have an answer today. We need to understand what you were proposing to do, what the process that

you're proposing to engage in looked like here before we could get you answers about how we're going to control Privacy Act-related information and maintain the confidentiality of that. I think there's several ways we -- we might achieve that, but we need to have a better understanding of how you envision the process to be before we can then come to -- come into that and play the role that we need to play to support you, as well as to make sure that we do protect the confidential information, as we're all very much interested in doing that. So...

MR. GRIFFON: The -- and the next item, C-3, talks about requests for additional documents. I know that at the pre-bidder meeting the question was asked on the records, and I think primarily what -- what we've been envisioning happening -- what NIOSH has been envisioning happening is the -- for an individual case the -- the administrative record will be on a CD and distributed, if it's -- meets Privacy Act concerns. The other question would be additional documents relevant to the review of the case, and I believe Larry's said in the past that's -- many of these

documents may be available on the web site or by other means, or published papers that are readily available through other means, then the contractor would have to get them themselves. But there's -- there's guestions -- and this is worth highlighting because it comes up in the -- in the individual task, also. There's questions about the site profiles, the worker profiles, those databases, if -- if they can be remotely accessed or if the contractors will actually have to make provisions for traveling and working at the ORAU or NIOSH offices to do some of those activities where they're required to compare a case against a site profile, for instance. So we -- we just want -- wanted some clarification on what -- what means might be available for that.

10

11

12

13

14

19

16

17

18

19

20

21

22

Going on to the next page, D is the interface of the Board and the contractors with relevant experts and to the individual claimant. And I -- and understanding that last issue is certainly something that we need more discussion on, the access of the Board or this -- or our contractor, the contractor assisting us, to the individual claimant to do follow-up interviewing.

That's something that we removed from the task order contract initially until we had more time to discuss it, but I think that -- that many of us on the Board do want to discuss that further, and many of us are interested in it, so I just highlight that. Maybe we won't get to it today, but I think we need more discussion on whether -- whether we want access to individual claimants for the Board and the contractor, and if so, how we can possibly go about that. And if there is -- I don't know if there is legal restrictions or --

DR. DEHART: You may recall that we had discussed at what point in the system will we actually have access to the record, when will we want to review this record with the contractor. And it's my understanding we've agreed that it would be post-adjudication. So the case has been --

MR. GRIFFON: Right.

DR. DEHART: -- resolved, and now do we have access.

MR. GRIFFON: Right, that's a --

MR. ELLIOTT: Yes, for the record, let's just make sure that we're all on the same page, that your review of

completed dose reconstructions is actually review of the pool of cases that have reached final adjudication. So that means if there is a case that goes to appeal, it's not in that pool yet. And we have also talked at length about interacting with the claimants, and you know my feelings about that, so I think we're probably going to end up in more discussion about that, it sounds like.

MR. GRIFFON: Yeah, I think we will. So those are just laid out. The other -- the other portion of D is interface of the Board and contractors with relevant experts, and -- experts in quotes, which may include technical experts from the sites, former workers, worker representatives, and we discussed that. Also -- you know, this -- this comes into play in the task contractors, I -- these interviews may be conducted over the phone, but they also may want to meet with these people in person. We did talk about -- these would probably be -- it may be like at the Garden Plaza and not on the Oak Ridge site, necessarily. Although Bob Presley did raise a question during our discussions this morning that in the event that we wanted to

follow-up and it needed to be done in a classified room, then we would have those issues to -- to attend to, so -- and to get a classified room, obviously we have to be on a DOE facility.

MR. ELLIOTT: And with a classified member of the Board, which right now I think we only have one -- two. Two, maybe -- three? Okay. Don't know who all's got a clearance. We're not supposed to know that. Right? But we do have to make sure that we don't send people in who do not have a clearance.

MR. GRIFFON: Or, you know, a contr-- we -- we've had a proviso in the contract language that the contractor would have cleared people, so it may be that the Board members cannot attend that portion, you know, but the contractor may be able to do that.

Going on to Section E, inter-- interaction between contractor and designated Board members and the Board, this was a sort of an attempt to walk through how we saw this -- these cases being processed. So the first step is that the designated Board members and the -- and a contractor will work on a group of cases and -- and then -- the way we saw this sort of cycling through

possibly, and this is really, you know, preliminary I think, and maybe best-case, but the idea would be to select a group of cases -- and we said 25. Those go to one contractor, possibly more than -- multiple contractors, but a contractor and two designated Board members, which is also open for discussion, would then start a review process of those -- of those 25 cases say, for sake of argument, in two months or at the next Board meeting -- approximately two months was an estimate -- then this -- the designated Board members and the contractor would meet and discuss those individual reports, which we brought up yesterday the -- the individual dose reconstruction reports versus the summary reports, so they'd go through all 25 reports with the designated Board members. And possibly we said that this could be done like the day before the actual Board meeting. Then they would -- would -- and they may have this compiled beforehand, obviously, but they might have a summary report, also, and once the designated Board members and contractor are in agreement, then they would bring that summary report to the full Board. And the summary report would be a de-

10

11

12

13

14

19

16

17

18

19

20

21

identified version and would look more at aggregate results than the individual cases. So that -- that was sort of the way -- and then the final step would be --I think this covers E and F, too. They overlap a little, as I looked at it this morning. The final step would be that then the Board, on a periodic basis, would report out on -- on our findings to HHS, and that would also be obviously in a de-identified form. And I think that sort of steps through E and F. And then G is -- finally the Board recommendations -this also overlaps a little. The Board recommendations to NIOSH regarding the individual case or aggregate findings was another one of my discussion items yesterday, and we -- we did say that there may be cases where the Board makes recommendations to NIOSH regarding a single case, and that may be -- most likely limited to a case where it would -- it would affect the outcome of that -- of that determination -- or affect the final outcome. On the most -- for the most part, I think the Board is going to provide NIOSH with recommendations on the aggregate findings and trends and things like that. I also say in here the Board

10

11

12

13

14

15

16

17

18

19

20

21

will track the recommendations to NIOSH and NIOSH's subsequent actions or responses to the recommendations, and the Board will include a summary of findings, recommendations and corrective actions within their report to HHS. So this was sort of a way -- we discussed a lot of these things in the past. It was sort of a way to lay out a real rough preliminary draft of how we see it maybe processing through.

DR. ZIEMER: And this requires no action today, but are there additional questions for clarification purposes that any of the Board members wish to ask of the subcommittee -- it's not a subcommittee, it's a working group. I've got to get my terminology correct.

Okay. Thank you, Mark. The two drafts of review forms we probably don't need to go through 'cause they are -- they are supportive of this. They're simply a --

MR. GRIFFON: Right.

DR. ZIEMER: -- step-by-step sort of identification of the issues and the findings and observations. It's simply a form that would be generated in the process of doing the reviews. And then what about the two -- the task order --

MR. GRIFFON: The -- yeah, the task --

DR. ZIEMER: -- items?

MR. GRIFFON: -- the tasks that I've laid out here, they -- they will look very similar to the language we've already discussed and which was in the original task order contract. On the first one, the individual dose reconstruction review, at the very end of it I put just a few items for us to think about, whether -- whether and how we have to build it into the individual tasks for the purposes of the contractor being able to make a bid on this. You know, their required travel, access to data -- some of these same questions, you know, to the extent that some of these answers would affect how the contractor could bid on this task, we need to flesh them out a little more.

Also I said -- as next steps, I think before the next meeting, I would hope that we could take these two -- two tasks at least and work with NIOSH to -- to draft them -- you know, to put the other language that we need to make them an actual task -- all the other contract language that needs to be included within this. So that was the -- the hope was that at the next

meeting we could present a more formal task. The other task is the dose reconstructions procedures and methods review. The A through -- A through H or so -- let me just say, most of these, the list of procedures were in the original contracts -- task order There were some additions to this. contract. additions I don't think contradict the original task order contract, but someone might want to examine that, The additions primarily were made by comparing a list provided by ORAU to the working group of the existing procedures that they're either -- that they've either developed or they are developing, so it gave us a sense of what -- you know, to -- a different level of specificity, I guess, that we could add to this task. And so that's -- that's about it. And I think --

DR. ZIEMER: Okay.

10

11

12

13

14

15

16

17

18

19

20

21

22

MR. GRIFFON: Like you said, we don't expect --

DR. ZIEMER: Now does --

MR. GRIFFON: -- action today.

DR. ZIEMER: Does the working group wish to have comments from Board members and -- before our next meeting, either questions or comments so they could

feed them to Mark?

MR. GRIFFON: Yeah, that would be --

DR. ZIEMER: We have a question here. Tony?

DR. ANDRADE: More of a comment, perhaps suggestion. I looked over both of the draft task orders. It's pretty standard. We've been over this stuff often enough. It's procedures and methods review and then basically a -- the first level -- a description of the different types of reviews that might take place. I was going to suggest that perhaps we turn it over either to the project officer or to the contracting officer and maybe get out a draft so that we can look at what one of these -- or both task orders may look like in near final form and that we then proceed to comment and work on them during the next meeting.

DR. ZIEMER: This is -- this is a good suggestion, and we -- we can probably have both things happening. If there's something that jumps out at you on this draft that you think should be addressed, you can let Mark know. But as Mark has already suggested, he's going to work -- I guess with Jim Neton or the staff people to get whatever language is necessary for the final task

order in terms of the Federal requirements. It seems to me some of the issues -- particularly this issue of the interviews -- is one that we may want to think about dealing with that in some way that would not hold this up. I have a hard time envisioning us getting into any interviews early on in this review process, but I'm -- I'm suggest-- I'm asking whether it would be possible to -- well, at least in the initial task order -- I guess you don't have any interviews involved in the initial task orders, do you, or --

MR. GRIFFON: It doesn't necessarily mean I don't want any.

DR. ZIEMER: I understand --

MR. GRIFFON: It's just that we're --

DR. ZIEMER: I understand that. But -- but I think we have to think very seriously about cases that are closed in terms of what that means even to a claimant, whether the claimant is successful or unsuccessful, if -- if -- we already know that interviewing claimants has been, in some cases, rather traumatic anyway. And I'm not -- it's not obvious to me what we gain by this at this point. But you know, I'm certainly open to --

if there's something in the record that makes it awfully clear that we just need to get back and find out --

MR. GRIFFON: Well --

DR. ZIEMER: -- you know, or say that something doesn't look right, that's -- but I'm a little nervous about the idea of -- of going back to a claimant whose case is closed --

MR. ELLIOTT: Let me comment on that.

DR. ZIEMER: -- 'cause there's -- there's a lot of personal things involved in this in terms of people coming to closure, whether it's -- whether it's pro or con, coming to closure with something that gets reopened, that's a very -- you know, it involves sickness, in some cases deaths and so on, so we need to be sensitive to that part of it, as well.

MR. ELLIOTT: I'm going to jump in here again. You've heard me speak about this before. I fully agree with what Dr. Ziemer just said. I firmly believe that you should conduct your audit looking at the informational materials that support the decision. In that process of your review, if you identify issues associated with

the interview process, that then may trigger the need. You can establish perhaps the need to interact with claimants. But frankly, I'm -- I'm not -- I'm not in a position to say that you're going to be able to interact with claimants. There are -- as I related to you in the past, there are a host of issues associated with that after the decision. There are materials. There is -- there are documentations that support the interview interaction with claimants that you'll need to avail yourselves of in your review, examine those materials, the way the interviews were set up, the way they were conducted, the reports that were generated from the interviews. All of this is information that is supporting of the decision. That, in our opinion, is what you should be reviewing and evaluating for quality and credibility.

DR. ZIEMER: Okay.

10

11

12

13

14

15

16

17

18

19

20

21

22

MR. GRIFFON: Can I --

DR. ZIEMER: I don't know that we want to have an extended debate on this issue today because we're going to revisit these documents at our next meeting, but -- yeah, Mark.

MR. GRIFFON: Just one thing to think about. I know it's a longer debate, but -- I mean I think there were other alternatives offered on a way to maybe get at this issue. And one, which is not being -- certainly is not being done right now, but it would be to transcribe or tape the interviews that NIOSH is doing and then the contractor and the Board would have something to turn to to review that -- you know, other than just the final written, you know, questionnaire form, so that may be one way to get a more in-depth review of the actual interview itself. But I -- I understand the issues, but I also -- I also reflect on some of the findings in the NAS report. And notwithstanding Larry's -- you know, and I understand the intent of NIOSH to involve and to get information from the workers, but I think we also have to keep our eye on that, that that -- you know, that's one of our roles is to make sure that that's being done in an adequate fashion.

DR. ZIEMER: Tony?

10

11

12

13

14

15

16

17

18

19

20

21

22

DR. ANDRADE: Quick comment. I think in the spirit in which we first decided to go forth with this auditing

contract that if it truly is going to be a quality audit on -- on what -- on the procedures and methods that we were using, then let's not forget about the fact that our findings really and truly should be used to continuously improve our processes. And in that sense, it's a forward-looking type of audit. If we find deficiencies, then those deficiencies should be pointed out to NIOSH for improvement in the future. And again, going -- I think going back retrospectively is a mistake, so that's just something to think about.

DR. ZIEMER: Robert.

MR. PRESLEY: Bob Presley. I go along with Tony, and you just go back and don't forget this. To us it's a very important thing. Maybe between Larry's group and the lawyers, that they can come up with some wording that this would be left open, with the fact that we come and, as a Board, ask if we do see fit to interview somebody, but leave this as an open -- open-ended thing, don't close the door.

DR. ZIEMER: Any other comments? Yeah, Roy.

DR. DEHART: A different topic. Larry, do we need to have any kind of training, since we're going to be

working directly with the contractor? As we sit and work over that, we're going to have the contractor there. Do we need any precautionary instruction or whatever? That -- just keep in mind that -- that question. I don't know.

MR. ELLIOTT: I will keep in mind that question. At this point I'm lost with what -- you've had Privacy Act training, you've had -- you've had that. You've signed -- you know what you're committed to in that regard, and the contractor will be held accountable to that, as well. But yeah, if you think of something that you think merits training or you're curious about do we need training to interact with the contractor, let me know and we'll --

DR. DEHART: Don't misunderstand. I'm not asking for training. And secondly, we did talk last time about the fact that we, as a group, will need training on the data access systems, and we need to keep that in mind.

DR. ZIEMER: Okay. Again, we're not taking specific actions. You've heard the comments. We'll work further to develop documents that we'll act on formally at our next meeting, which we'll be talking about a

little later in terms of when that will be.

PUBLIC COMMENT PERIOD

Now I'd like to move on. We're just a little bit behind schedule, but we have our public comment period. I have several individuals who've requested to speak. We're going to begin with Carl -- Carl Scarbrough, I think, if I'm reading this correctly, Carl, Atomic Trades Labor Council -- president of Atomic Trades Labor Council, and if you'll approach the mike, please. So Carl, if you'll approach the mike, we'll be pleased to hear from you at this time.

MR. SCARBROUGH: For one thing, I'd like to welcome you to Oak Ridge, and we appreciate having such a honorable group here. What I'd like to appeal to you -- for fairness on this thing. And we're dealing with people that are sick. Some of them are dead. Some of it's real personal. We've got people dying that, you know, there's no compensation. I personally think \$150,000 is kind of cheap for a person's life. Of course that's something to talk about later on. But what I -- like I said, I'd like to appeal for fairness from you. And some of the decision-making -- for instance, I

represent X-10 and Y-12, everybody except the guards. There's different unions. And right now probably less than five fingers'll be the ones that's got compensation, and there's 10,000 people working -current workers, and there's got to be that -- that many or more retirees. And so something you can count on one hand that's been going on for quite a while means we're not doing a whole lot very fast. NIOSH, you know, is making some of these recommendations on data, and then they turn around and they really say they don't have complete data. then the individual has to come up with data that he has no control. I mean I can't go anywhere unless somebody comes up to me and says how am I going to do this? Like I run into a guy last night, 11:00 o'clock. Hey, he said, I know you. I didn't know him from Adam, but he's -- he said I put in for this compensation program, and they tell me that -- it's for his father, and they tell me that I've got to find my father's -- somebody he worked with, and I've got to have all this information, and I don't know who my father worked with. And of course obviously wherever

10

11

12

13

14

19

16

17

18

19

20

21

you go to ask this, they don't know who they worked with. Of course I recommended he go to his father's local union and maybe they can come up with something. But we're really loading these people up.

I think one of the hardest things we're doing is the expectation they're going to get paid. Other words, you've got -- I don't know how many thousand people out here. Do y'all know how many from Oak Ridge that's signed up? It's a pretty big number. Right? You've got 3,000 people, every one of them thinks they're going to get \$150,000, for whatever reason, justifiable or not. And at X and Y right now, that's what I'm asking for the fairness, you know, they don't work in a gaseous diffusion plant. What's the odds of them getting -- under -- under the criteria you have now, of them getting the compensation? You know, if it was you, could you prove everything you need to to do all this compensation program? Now if you worked at K-25 or a gas diffusion plant, if you got lung cancer, you pretty well got -- you don't have to prove that. you see where we're coming from, and there's a lot of contradictions in this data that's out here. But like

10

11

12

13

14

19

16

17

18

19

20

21

I said, I'd like to appeal to you all for some fairness. I know you've got a big job. You've got a great big ol' boy over here on the end here, and I know he's going to take care of all of our business. count on you, can't we, Bob? Okay. He said he didn't have but one vote, but he had all of you in the palm of his hand. But anyhow, I appreciate it and give these -- play like these people are your -- might be -consider it's you, your brother, sister, mother or daddy and that -- take it to heart where we're just not a bunch of numbers out here. Appreciate it, thank you. DR. ZIEMER: Thank you very much, Carl. Next we'll hear -- let me ask, any of the Board members have any questions for Carl? Bob, I think Carl just wants some barbecue ribs is what he was after. Next we'll hear from Bob Tabor. Bob's been with us before. He's from Harrison, Ohio. Bob, welcome. MR. TABOR: Yeah, for the record, Bob Tabor, Fernald Atomic Trades and Labor Council, and I'm pleased to be here once again. I want to reiterate some comments that I've made a number of times in the past, but it

10

11

12

13

14

15

16

17

18

19

20

21

22

seems like the urgency again is before us and possibly

it may have some bearing on an issue that Mary

Schubauer-Berigan -- I think that's how she pronounces
her name -- Mary, okay. She brought up an interesting
thing in one of her slides here was the issues
regarding current workers, decommissioning and
decontamination era workers may face different hazards
and health effects, and I definitely agree with that
because Fernald is a closure site that is definitely in
full blown closure. I mean we're just right around the
corner from, you know, having it done.

There will be some tasks that will continue into what we define as completion, which is a little different than closure. And there will be some post-closure activities. But just about all the work that's being done out there really is cleanup and totally, you know, true environmental remediation and decommissioning and decontamination of these facilities is something that's ongoing on a regular basis.

Now the regular work force -- as the regular work force, I'm referring to the Fernald Atomic Trades and Labor Council represented folks -- those folks are not highly engaged in the final decommissioning and

decontamination aspect of these buildings in these facilities. The contractors bring in other workers and other work forces to do that work, and they are short-timers, as we put it, and I can't speak to possibly the adequacy of the radiation and health monitoring of those particular facilities. But obviously, as she pointed out, this is something of great importance. When it comes to facilities that my workers are involved in, we're somewhat of a work force that's a little bit more astute to the processes and have a little bit more insight and knowledge of on-site monitoring and surveillance and so, you know, we are always looking at those aspects of the project to be sure that they are adequate.

But the whole thing here, and this gets to my point, is the information -- the information that may be needed in the future to -- to look at the issues regarding the current workers and regarding things with decommissioning and decontaminating of these buildings, that information -- I'm not certain, with respect to how available that it will be. And I know there's only so much that you folks can do as far as in the past I

have asked you to look into whatever avenues we have to -- to have our government reissue some assurance that the necessary information can be retained, and I -- and this Board I believe did write a letter to that effect, as I recall, and I appreciate that. But most recently at my site -- and I do not have it with me, unfortunately -- we had a memo that was put out that concerned the retention of information and the responsibility of who needs to retain what. specifically alluded to the things that the DOE would be responsible for retaining. But the interesting point of that communication and that I want to tell you about is that it alluded to the fact that the current contractor and all the stuff that pertains to his ongoings, and that may -- I don't know if that includes medical surveillance and things like that; it probably would not, but most of the project activities, all those type of records, he is fully in charge of. Now that brings me to the point of well, what is the retention time, how may they dispose of those, are those records going to go with the contractor, what information will that contractor still have concerning

10

11

12

13

14

19

16

17

18

19

20

21

the processes of decommissioning and decontaminating of these buildings and other things and operations in the downsizing of the project overall and things that might allude to, you know, the physical ongoings that might have a bearing on profiling this particular site or have a bearing on, you know, any information in the future that would be pertinent, not just in the development of what you may need as far as future claimants, but in the development of studies that they alluded to here. I just wanted to raise the issue to put you on notice again that these are serious issues at these sites that are -- have a short life now and -you know, and if there's going to be -- if you anticipate there's going to be information that you may need in the future, there may be some avenues that you may want to pursue or look at to assure that the kind of information you may need in the future will be attainable. So there's a major concern here. you.

10

11

12

13

14

19

16

17

18

19

20

21

22

DR. ZIEMER: Thank you, Bob, for raising that point.

Again let me ask if any of the Board members have questions to address to Bob?

Thank you, then we'll move on. Owen Hoffman has a comment. Owen addressed the Board yesterday as part of the formal presentation. Owen, from -- with SENES Oak Ridge.

DR. HOFFMAN: Hello again. The comment I have to make is rather inspired by the excellent presentations by David Utterback and Mary Schubauer-Berigan on the worker epidemiological programs, both those completed and underway. Several of us are intimately involved with the beginnings of this. Paul, you as former Undersecretary of DOE for environment safety and health, and I think you presided over the transfer of authority from DOE to HHS in this matter, and I think it was at that time that you were engaged in the distinction between analytical epidemiological research and descriptive epidemiological research. Gen, you served, as I did, on the advisory committee for energyrelated epidemiological research to the HHS to oversee progress in both the environmental off-site and for worker studies. And of course Larry, you and I go back almost to the beginning of those days when I -- when I would ask for the -- informing workers of the risk of

10

11

12

13

14

19

16

17

18

19

20

21

their exposure, even when those risks were below limits of epidemiological detection or below regulatory standards.

My concern is this, is that there is a organizational disconnect between the occupational safety program and the needs for epidemiological research. Congressionally mandated in your work, but I don't know the extent to which this Congressional mandate supports -- has a support mechanism to ensure the right epidemiological research gets conducted. The Advisory Committee for Energy-Related Epidemiological Research, under your initial program, no longer exists. as I understand, David Utterback and his group, which is known -- I don't like using acronyms so I -- it's known as the epidemiological branch -- all that funding comes from the Department of Energy, and the mechanism for that funding is still under this Memorandum of Understanding, but there is no constituency, there is no advisory board overseeing whether or not the funding's adequate or whether or not the spirit of the Memorandum of Understanding is being honored, whether or not there are incentives put in place to go slow in

10

11

12

13

14

19

16

17

18

19

20

21

these areas. And so given this legacy that we all share, I thought I would take this opportunity to just sort of publicly state my concerns that there is this disconnect, and my concern is that these studies -- although they're answering the -- their attempt is to answer the right questions -- whether or not they're sufficiently funded to ensure that the answers come forward in a timely manner.

Now I'll make one last comment. Paul, Gen and I, we go back a long ways. The three of us are members of the Health Physics Society. Gen, you gave a presentation about two years ago -- two years ago this month to Congress, informing Congress there is no epidemiological evidence to support risk below about 10 rem effective dose. There are a few people who have benchmarked off that information. Now in the epidemiological evidence coming forward under NIOSH, is there support for this, or is there new information that would draw into question whether or not the limit of epidemiological detection is at 10 rem. So I start with more of an urge -- a plea for ensured support for your programs, and with the next question, which is a

technical question, as to whether or not our state of knowledge has improved from that of let's say two years ago.

DR. ZIEMER: We may have to consider those rhetorical questions, 'cause I'm not sure anyone has the answer to that. They're very thought-provoking remarks, Owen. We appreciate that. Again let me ask if any -- okay, Gen Roessler wishes to respond or --

DR. ROESSLER: I'll respond in this way, Owen, to your second comment. If I were making that presentation next week, I would do research, as I did at that time, and find out what the appropriate number is.

MR. GRIFFON: I would also ask if -- if Owen had an answer to his own question.

DR. HOFFMAN: In -- in terms of a constituency or mechanism to ensure the Memorandum of Understanding is preserved, the answer to that is no, I don't think that mechanism exists. It needs to be rebuilt.

The question in terms of evidence for risk below 10 rem, I believe it exists, and I believe the -- in fact -- in fact, from the NCRP review of low-dose studies, we know that in utero exposure at one rem will induce

cancer in later life, and so the lowest that I currently know about is about a one rem limit to -- as a limit to epidemiological detection. But I -- but maybe this question goes to Mary or David as to whether in their studies they are seeing evidence for effects at doses substantially below an effective dose of 10 rem.

DR. ZIEMER: Well, I'm not sure they are zooming to the mike to answer that, either. But the debate's going to go on. I'm going to answer for them in the sense that it's -- it's going to be a long time before epidemiology answers the question, for example, is there a linear no-threshold response, which is a big debate nowadays. In fact, I'm -- I'm a little pessimistic about whether epidemiologists can answer that, and during the break I reminded some of my epidemiology colleagues here -- I call them colleagues. I'm not an epidemiologist, but a colleague who was told me that an environmental catastrophe is one that is so great that even an epidemiology has a much easier time at higher dose -- looking at dose effects at

higher incidence -- or higher doses.

MR. GRIFFON: Must be a good health physics joke.

DR. SCHUBAUER-BERIGAN: That's right. You can laugh at our expense. We're tough, we can take it.

You're addressing very important questions, and those are precisely what drives our research program. And although I didn't make it explicit enough, that's exactly why we feel it's important to design studies carefully and to combine cohorts to increase the statistical power to see low effects that might be expected at doses in the range of one to, you know, 10 rem. Individual studies have shown suggestions of effects below 10 rem, in my opinion, but in terms of a consensus in the general public, you've -- you know, that you've clearly touched on an issue that is of great importance and one that we feel we can be better equipped to address as we complete our research program.

DR. ZIEMER: Thank you very much. That's all I have for members of the public. Let me give the opportunity -- is there anyone else who didn't sign up that -- thank you.

MR. STEWART: How do, I'm John Stewart. I'm PACE safety rep at ETTP. I've heard enough technical, can I just ramble on for a little bit? I remember back in the early nineties, I guess maybe even early eighties, talking to a fellow worker -- I'll use his name, Jimmy Walls -- and he described in building 1131, the feed plant, where the system messed up and started backing up and spitting product in the floor. Of course he was on evening shift and they rushed them in there with buckets and shovels, no protection, shoveling this product in the buckets and hauling out. The next day they asked for some safety equipment. They went to a sporting goods store and bought them hip waders, still buckets and shovels.

Now I've looked and I can't find any records of that except for talking to Jimmy Walls, said he was there and he did it. But interestingly enough, 1131 was one of the first buildings DOE tore down. It's got a asphalt cap on it now where it used to be.

Another bit of rambling, a friend of mine -- another friend of mine named Don Arp came to my office I guess October two years ago, said he needed my help. I knew

he'd been to the company physical about two months before and they'd said he -- perfect health, a little overweight, maybe some onset of diabetes because of that. Other than that, no problem. I said what can I help you with, Don? He said well, I just came back from my doctor, and he said I've got three months to live. He had lung cancer, stomach cancer, colon cancer, intestine cancer, just ate up with cancer. And we started -- he said now if I take the chemo, which I'm not going to do, I can -- they say I'll have nine to -- nine months to a year. So we started and, you know, you can -- if you have a letter from your doctor, you can get half your life insurance in advance and we set up an annuity. He was worried that his wife, which had never handled the money, would be left penniless. We set up an annuity where she was almost guaranteed she couldn't go through the money and waste it. quess my point with Don is -- I said what we need to do after everything -- this is over with, we need to go ahead and file this for this compensation, get that in the works, so we did. The letter came back from DOE says -- remember, he'd been there 27 years, and when

10

11

12

13

14

19

16

17

18

19

20

21

the letter came back he was on short-term disability for cancer, said we cannot find any proof to verify your claim that you've ever worked at a DOE facility. A fellow worker, still had his badge, his badge number, no proof. Of course we got that -- his widow subsequently got the money. We worked through that. That doesn't say too much for DOE, in my opinion. dose reconstruction, if they can't find your employment records for someone that's there now, how are they going to go back 40 years ago, Larry, and find something? You know, we feel like -- almost like the Israelites that have left Egypt and now we're out in the desert trying to find the promised land and don't know -- we have meetings and meetings and more meetings. And we're using -- being used for guinea pigs and they're doing studies and all kind of results, all kind of studies, still got people dying. I noticed in yesterday's paper Frank -- he's not here now -- over in Iraq. I think President Bush said that fighting war was over about two weeks ago. Set up a program we're paying out pension benefits to Iraqis, what -- said two crisp \$20 bills. So in two weeks we

10

11

12

13

14

19

16

17

18

19

20

21

can pay the foreigners, and how long has this been going on? We can't have a program to where the workers, they're sick and their families that are suffering financial loss cannot get any compensation from the government. I'm like Bubba, I think the \$150,000 -- almost a slap in the face. So again, as I've said at every meeting, you know, we need to get off square one and get moving and get some kind of a -something for the workers so they can have some kind of a benefit that it won't destroy their families financially 'cause they're -- when I worked at the Resource Center when we first started, had such overflow they had some of us up there working, I had people that came in, put in for benefits, helped fill out their form that I had worked with, younger than me, that were so ate up with cancer I didn't recognize them, didn't -- till they told me their name, didn't even know them. You know, we're -- we're -- all the epidemiological studies, all the meetings we're having, this is all great. But the workers feel like we're being guinea pigged to death. You're studying our records. You're studying our health. You're studying

10

11

12

13

14

19

16

17

18

19

20

21

how much doses of radiation it takes to cause our cancers, and meanwhile we're there dying and not getting compensated for it. Thank you.

DR. ZIEMER: Okay. Thank you very much. Those are sobering words, indeed.

Commenter here?

MS. AYERS: Good morning. I --

MR. ELLIOTT: Can you state your name for the record, please?

MS. AYERS: My name is R. L. Ayers, initials only, R. L., and I'm here just to ask you all a question. I didn't have a prepared speech or anything, didn't even know this meeting was going on until I went by the union hall and he told me over there. He said you -- maybe you should go down there.

What I want to know if -- my husband worked at K-25 plant. He worked there from 1971 until he retired in 1985, and of course he died last year in November, and he died of silicosis. I've never heard anybody even mention any compensation or anything for silicosis, but that is a deadly disease. There is no cure for it.

And that's what he died of. I called Ms. Yvette Waters

down in Jacksonville, Florida and she told me that if he worked in Alaska or Nevada that is the only way that they would pay for that disease. I wonder if it will ever be added to the state of Tennessee compensation plan for these plants here, because he had never been to either one of the places, never. And since 1943 he'd worked in this area. When he went to K-25 in '71 -- of course my husband was a concrete finisher and he worked at Y-12 and X-10, helped them build it, but when he went to K-25 in the plants in '71, he didn't have silicosis at that time, or it didn't show up at that time because they would have never hired him. They was kind of strict then on hiring people, because I worked down there. And now they tell me that they won't pay for it. And I just wonder if anything could ever be done about that. Thank you.

10

11

12

13

14

19

16

17

18

19

20

21

22

DR. ZIEMER: One of the Department of Labor individuals may be able to address that.

MR. TURCIC: Yeah, that's correct, silicosis is only --

DR. ZIEMER: Please identify for the record --

MR. TURCIC: Pete Turcic, Department of Labor.

Silicosis is only covered for individuals who worked

mining the tunnels for the underground test sites at Amchitka in Alaska or Nevada Test Site. However, and Shelby had mentioned yesterday about subpart D of EEOICPA, which is a -- it's administered by the Department of Energy to provide assistance to claimants for other toxic diseases, which would include silicosis, to get State Worker's Comp.

MR. STEWART: Can I follow up? This lady's husband I worked with. During the centrifuge program, when we manufactured the tubes, we used silicon sand when we sandblasted the inside of those tubes, every one of them -- hundreds of them. No telling -- I would say most everyone at K-25 was exposed to silicon sand at some time 'cause it was -- from when you blast with it, it made a dust. It went all over the site. Sure, we can do part D. What we've got, 16,000 waiting for the doctor's panel and there's I think what, 14 of them gone so far? Yeah, but there's -- probably 20 years from now they'll get to you.

DR. ZIEMER: Any further public comments? Okay.

Before we break for lunch I'm going to turn the mike over to Larry Elliott to raise an issue related --

actually related to yesterday's public comments and the issue relating to when site characterizations might be completed and some related issues. Larry, if you would raise this point to the Board.

MR. ELLIOTT: Thank you, before I jump in on that, I would like to make an announcement for the Board and for the public, at the behest of Michael Schaeffer from the Defense Threat Reduction Agency so you'll all know that the Department of Veterans Affairs Committee on Environmental Hazards will meet in June 3rd and 4th, next month, at -- let me get my cheaters on here -- at 811 Vermont Avenue, N.W. in Washington, D.C. meeting starts at 9:00 a.m. on both days. For further information or to obtain the agenda for that, please call Dr. Neil Ochin, M.D. at 202/273-8452. That's the Department of Veterans Affairs Committee on Environmental Hazards. I'll be attending that meeting as a liaison from this Board to that Board in case they have any questions. We will also have on our web site a link that'll link up for this particular meeting and agenda.

10

11

12

13

14

19

16

17

18

19

20

21

22

Now I wanted to raise an issue with the Board to get a

sense of where the Board stood. And this goes at the heart of appearance of conflict. We're fortunate enough in our contracting team with ORAU to have several individuals who were instrumental in -- and integral in development of dose reconstructions for the Mound site. These dose reconstructions were conducted for a different purpose than our dose reconstructions for compensation, but they're very much of interest to us and very applicable and these individuals are very knowledgeable about the Mound site.

In the spirit of good management practice, good management control and efficiencies that we're trying to achieve in finishing claims and moving cases over to DOL for final adjudication, and in our effort to try to achieve 6,000 against our backlog by the end of this year, I would like to be able to ask the ORAU team to task those individuals with direct effort on individual dose reconstructions, and still maintain the process that we have put in place with the help of this Board whereby the claimant still has the opportunity to speak up about who is assigned to do their dose reconstruction. It just seems to me that without

utilizing these experts, we do ourselves a disservice. It goes beyond just the Mound plant. I have on my staff experts from Fernald. I would like to be able to see those experts be assigned to do Fernald cases. would like to be able to rely on the claimant to say wait a minute, I got a problem, and according to the way your operating procedures are characterized, I have the opportunity here to take exception to that individual and request another individual be assigned. I think that gives us enough control and protection about appearances of conflict of interest, and would allow me to make sure that we utilize our resources effectively. Right now we're a little bit concerned about whether or not the Board's perception of this or how you view this would survive in your audit, whether or not if you saw a number of health physicists, dose reconstructionists who are assigned to individual dose reconstructions, working on those, and whether or not that appearance of conflict is too heavy in the balance. So I'd just appreciate hearing a little bit of discussion from the Board in trying to get a sense -- a sense from the Board as to what your views are in

10

11

12

13

14

19

16

17

18

19

20

21

this regard. Thank you.

DR. ZIEMER: Let's start with Tony here.

DR. ANDRADE: I really think that, for all the reasons that you mentioned, especially efficiency, but more so than even that, because of their -- because of the expertise that they've built up having worked doing dose reconstruction in the past, it would be -- it would be a sad waste in not using those folks to go back and help us get going and moving at a faster rate in completing dose reconstructions.

Having said that, let me also remind the Board and the public that the auditing that Mark and his colleagues in the dose reconstruction working group have put together are those folks who may not ever have had work associated with sites previously, and so that helps in going back to check fairness. It helps to go back to see if there could be any -- any instance in which some sort of favoritism is being placed. So I think that we have checks and balances in place or that we are just about to put in place that would help us out in this regard, and so I really feel it's an excellent suggestion to go forward with.

DR. ZIEMER: Wanda.

MS. MUNN: Failure to take advantage of known expertise with respect to activities on any site can only have the effect of lengthening the process, which I do not feel is the desired outcome by either this Board nor the claimants. If there is a perceived concern with respect to the trustworthiness of the reviewers to recuse themselves in cases where they may have had any personal contact or even knowledge of the individual case, then it appears to me that it could be -- that particular concern probably could be met with a statement of -- of recusement, essentially, by the individual. Otherwise, there is an issue of institutional knowledge that simply cannot be rapidly accumulated by other individuals. It would be a shame to lose that professional capability.

DR. ANDERSON: I guess it's hard to really comment without looking at the specific review. I think there were -- there's a set of conflicts of interest and bias sorts of things set up that I think it's important for us to apply uniformly across the board and not say well, we're running behind. Now let's, you know, scrap

the procedures and we think in this case it's okay and in that case it's not okay, so -- and I guess I wouldn't want to rely solely on the challenge that an individual can have because they may not know the individual and have had no experience, and I would expect there'll be very few challenges to that, so they're to expect that now we put the burden on them to say do you want this person or not, I think is somewhat problematic. So I would say it's somewhat of a slippery slope as to when does it become a significant conflict and when does it not. And without knowing what the work the individual did and I think that there is some subjectivity to deciding should they be excluded or not. I thought at one point we'd talked about these individuals. We wouldn't lose their expertise, but they wouldn't be the lead reviewer, that they'd be available as a consultant, that if you had questions about it, that individual, they'd be there, they'd be available just as, you know, a set of experts who, you know, aren't -- haven't been hired or are workers that could be consulted as opposed to be the lead constructionists. So I think we'd need -- you

10

11

12

13

14

19

16

17

18

19

20

21

know, I think having some flexibility in it might be helpful, but I think we really do have to stick to criteria that have been developed. And if NIOSH feels that there isn't a conflict, just as dealing with Board issues, you make that determination and I think, you know, whether we would do that and then subsequently through an audit disagree, that would be a thing. I think it's really up to NIOSH to decide. think there's -- is the balance here greater one way or the other. Now if the dose reconstructions they were doing, not part of this, were part of a lawsuit, you know, then I think that might be something that people might find suspicious. So if it was part of a research project, that might be something totally different. DR. ZIEMER: Larry, can you clarify or maybe give some more concrete examples? Are we talking about

more concrete examples? Are we talking about individuals who, for example, did dose reconstructions as part of a research project from outside, as opposed to individuals who were workers on that site, or do you have a specific --

MR. ELLIOTT: Well, it covers --

DR. ZIEMER: Or both.

10

11

12

13

14

19

16

17

18

19

20

21

MR. ELLIOTT: -- the waterfront, and certainly at the Mound site, that set of dose reconstructions, over 2,000, were done as part of a settlement, I believe, in a litigation. We're -- I'm not proposing that we change the conflict of interest plan that the ORAU team developed and was part of their proposal, and then further developed as the Board reviewed it and got engaged in all of this, still holding up the claimant opportunity and ability to take exception to that individual assigned to do the dose reconstruction. we're so limited, so limited in the number of qualified health physicists that we can bring to bear on this, the way the site profiles will -- we're proposing to get developed, I can just see a need to have the ability to say -- unless it's -- the assignment is challenged by the claimant, it's a good utilization of resources. It's not only the individual dose reconstructor, it is the reviewer who reviews on top of that person's work who reconstructed the dose. to my staff, who some -- you know, have -- some of my staff have backgrounds within the DOE system at certain sites, some don't. I'm just trying to get a sense here

10

11

12

13

14

19

16

17

18

19

20

21

of the Board as to how best to utilize the limited resources that we have and get the job done effectively as possible.

And let's remember that what we talked about earlier is zero tolerance for actual conflict of interest, where somebody intentionally does something. We have no tolerance for that. We're monitoring that very closely. What I'm getting at is the appearance of conflict. You heard about this in Paula Kocher's slides to you this morning about appearance of conflict. It is different than actual conflict of interest.

DR. ZIEMER: Mark, did you have --

MR. GRIFFON: Really I think Henry hit most of my points. I -- I just -- you know, the slippery slope thought was going through my head as Larry was presenting the Mound example, and then he -- you know, I was thinking could this be a slippery slope, and then I think he answered it by adding on Fernald. I mean I'd be concerned that -- and I was under the understanding that Henry was, that -- that these people could still be used as resources, as tech-- so -- so

the team would not lose their expertise from the sites, but that they would not -- I think having them available as the lead dose assessor would be problematic. And even -- even from the standpoint that if they've done dose reconstructions already, I think human nature might make it difficult for them to find a very different result the next time through, so they might not be so critical of their own past work, so I think another reviewer to come in -- that's part of the concern from -- from past activities, past studies that have been done. You know, there's always been at least some of the public concern about the adequacy of those dose assessments that were done, exposure assessments that were done, and if you have the same people doing them again, I think there'd be -- that -- that perception would be even stronger, so...

DR. ZIEMER: Rich, you had a comment?

10

11

12

13

14

19

16

17

18

19

20

21

22

MR. ESPINOSA: Well, Mark and Henry are saying that -yeah, I agree with. As long as the dose
reconstructionist has the avenue to access somebody
with the expert, but I guess one of the things I don't
understand is the site profile. You know, somebody

that's from the site -- we're talking about Mound right here. I guess I don't understand if they can or can't do the site profile.

MR. ELLIOTT: We think they can do the site profile. We didn't think that was off the table. They are working on the site profile. That's how to apply their expertise. And that is going forward, whether it's the MJW folks working on the Mound site where they've done dose reconstructions for a different purpose before, or whether it's ORAU folks specifically who may be working on the Mallinckrodt site profile or technical basis document, but they have a -- you know, they have a vast experience and expertise with the data that's been collected on Mallinckrodt workers. We've felt from the very start that we could utilize that expertise that way. The crunch comes where we try to get 200 plus out the door a week, and we're limited in a -- you know, we have a site profile put on the table, technical basis document put on the table for Mound and we're limited in the number of dose reconstructors that we can assign, we're limited in the number of reviewers that we can assign to get those cases processed.

10

11

12

13

14

19

16

17

18

19

20

21

I spoke earlier about our monitoring for conflict of interest. Every one of these things that is finished gets reviewed by my staff. We're very careful about who we assign to review those. They cross Jim Neton's desk and I personally read every one of these and sign every one of these, and looking for a laundry list of things that we're checking for. So I think the controls are in place. I would like to be able to use the experts that I have at my disposal, not only to develop site profiles, but to engage in individual dose reconstructions using those site profiles.

DR. ZIEMER: Roy?

DR. NETON: I'd just like to comment specifically on the MJW issue at Mound. The situation is such that MJW possesses almost -- most of the internal dosimetry expertise on the project. It's divided between Dade Moeller doing external dosimetry and MJW doing internal. MJW did the bulk of the dose -- almost all -- did all the dose reconstructions at Mound, and ORAU has taken the very conservative approach in implying that since MJW did the dose reconstructions at Mound, they are organizationally conflicted, meaning no one on

their corporate staff or employed by MJW could do a dose reconstruction at Mound. So that -- that severely handcuffs us from moving dose reconstructions forward at the Mound site in particular. And that's just one example of a situation that I think may be an interpretation that they're not organizationally conflicted might help us out there.

DR. ZIEMER: And they're talking about cases where there may be individuals who were not involved in the Mound site, but it's a -- they're raising the issue of corporate conflict, simply because the person is working for them and they had other people involved in that dose reconstruction, so that's a very broad, as it were, interpretation of conflict.

Okay. Mike?

MR. GIBSON: With all due respect to the claimants that are not being paid and the system being bogged down, with all due respect to NIOSH and Larry and everyone else, I am adamantly opposed to this in any way, in any shape, in any form. MJW was brought in -- there was two different dose reconstructions. One of them had to do with a lawsuit, one of them had to do with a Price

Anderson violation where they were not monitoring workers correctly. The data that they took to do this dose reconstruction was old, was limited. They made assumptions that it was based on gross alpha. didn't go back and do a site profile to see if it was plutonium, to see if it was uranium, to see if it was any other isotope. I questioned the results of these dose reconstructions at the time. I had to FOIA over -- we brought this to bear. Our union was the one that had Senator John Glenn get a commitment out of DOE to come in and do this dose reconstruction, and it took them probably six or seven years to do it. They went on limited data. I -- they didn't do a site profile. I question -- I'm adamantly opposed to this in any way. I had to go through the -- an interview in the office of the President's general counsel to get a waiver of conflict for any issue to deal with Mound that I'd have to recuse myself from from this Board, and yet the same people that's made millions of dollars at Mound, we're going to let them try to do dose reconstruct -- redo dose reconstructions they've already done? How much extra emphasis are they going to put into that, and how

10

11

12

13

14

19

16

17

18

19

20

21

much are they really going to look at people who deserve compensation? Or are they going to look back to what they got paid to do, and that was to make it look like that they had repaired bad dose assessments. I'm adamantly opposed to this.

DR. ZIEMER: Okay. Thank you, Mike. Let's see who else had a comment.

MR. ESPINOSA: Actually it's not so much a comment, but you know, I kind of get the feeling of where the Board's at with this. I'm kind of interested in what the public is thinking on this issue, as well. So maybe we can get a little bit of public comment on this, I'd appreciate it.

DR. ZIEMER: I don't object to getting public comment.

We have gone into our lunch hour. We -- and we can -we can take this up again after lunch, if you wish.

Let me -- and Larry, you've seen there's a crosssection of views here. It's obviously not clear -clear cut. Well, it's -- there does not appear to be a
clear consensus one way or the other. I think -- I
think we have to, in this case, give a fair amount of
weight to some experiences that Mike has raised it

seems to me are pertinent here. I -- on the surface of it, I would have not personally objected to individuals simply because they worked for the company, if they had never worked on the site. But there is, I think, that sensitivity could be important that Mike has raised, so...

MR. GIBSON: I believe most all the people at MJW drafted to do this dose reconstruction did work on the Mound site.

DR. ZIEMER: I was speaking in generalities, if there had been -- the issue is corporate versus individual, but -- well, it may or may not, but you've heard the comments.

Let's -- let's recess for lunch, and let me tell you that this is an abbreviated lunch hour. Remember, we have a tour of Oak Ridge scheduled for 2:00 o'clock.

What we have after lunch -- we have Board review of the minutes, which we can get through very rapidly. I'm -- let me -- let me ask if there are members of the public who are -- who want to address this issue that we've just -- are there -- is there -- is there anyone in addition to Richard Miller?

Let us hear from Richard. Okay, Richard, why don't you go ahead and --

MR. MILLER: Hello.

10

11

12

13

14

19

16

17

18

19

20

21

22

DR. ZIEMER: -- if you promise not to take too much of our lunch hour -- no, we can do it after lunch if --MR. MILLER: Look, this got brought up after the public comment period. Okay? I don't know why Larry brought it up then, but he should have brought it up, 'cause this is such a significant question in terms of the management and the tensions that the program is grappling with. I don't think this is something that should be hushed. I think this ought to be put on the agenda for the next meeting. I think alternatives, in the spirit of NEPA*, ought to be explored here. I know that, just to reflect on my very first conversation with Larry Elliott about this program, I was on a conference call with Larry with Kathy Rest in her office in November of 2000, just after the law had passed. And I apologized to Larry for having worked so hard to make sure that NIOSH was going to get this responsibility because they didn't volunteer for it. But we had a commitment, and the commitment was that

for those of us who were advocates of this program who had specified and had convinced Congress that it was completely inappropriate to have the Energy Department do dose reconstruction, and there is specific proscription in the statute that says neither DOE nor any DOE official can do this. It was with some reservation that we saw a major DOE contractor wind up getting the contract to do dose reconstruction. It didn't violate the law, but it sure tempted one to think that this was getting awfully darned close to the edge.

But back to this conversation, because this very conflict was -- we were aware of for those of us who were advocates for this program, even while we were legislating. And the first suggestion that we made to NIOSH was please take some of the money that the Department of Labor is going to give you and put them into some ERCs or ERC-like institutions -- Education Resource Centers -- that NIOSH has for training physicians and go find a couple of institutions that do a good job training health physicists so that the Department wasn't -- Health and Human Services was not

dependent on such a shallow pool of expertise to fish from in terms of the conflict of interest problem. And I repeated this suggestion to Kathy Rest when she came here to visit us, and I've repeated it to Larry and NIOSH on countless occasions because this very moment was foreseen where we would be told that claimants would not get their claims processed because they couldn't manage the conflict of interest because the pool of expertise was too shallow.

This is not a newly-discovered problem which NIOSH has just encountered and now wants to try to swim through these very difficult waters by saying well, let's bring down the walls on conflict of interest. How many people on your staff worked at Fernald, Larry? How many have come to work to you from Mound because it looks like brighter and bluer skies? How many of the individuals who have been on your team here at Oak -- with Oak Ridge Associated Universities, who brings terrific expertise in the DOE, nonetheless is going to have to go back and render judgment on work that they or their colleagues will have done in the past? Even in site assessments, Oak Ridge Associated Universities

faces an extraordinary conflict. They did -- Betsy
DuPree* did the study on Mallinckrodt, just to use the
example you brought up, and Oak Ridge Associated
Universities had Bill Tankersley* working on this
project, as well. And here you have individuals who
are going to be doing site profiles which ultimately
are going to contradict the external dosimetry
potentially that were published in the Oak Ridge
Associated Universities studies. And we've said site
profiles are off the table, we're only going to look at
individual dose reconstructions.

I'm not sure, actually going the other way, that your conflict of interest screening is adequate. I think the question of putting it onto the claimants, who don't remember names, who don't know who did dosimetry, who worked in large institutions, is the wrong place. They are the check and balance on the system in case your conflict of interest system fails. That's why you're sending them the conflict of interest reviews. Conflict of interest reviews which, I would add for the Board's benefit, are not even fully published on the OCAS web site as we sit here today, nine months after

the Oak Ridge Associated University contract was awarded. We don't even have all the conflict of interest disclosures on the dosimetrists posted on the web site, and now they want to start to tear down even the public disclosure.

I have to say this, there is a solution. There's a NEPA-like solution if we want to step back from this problem, because I'm very sympathetic with the delay The solution is to expand the pool of people issue. who you want to invite in, whether it's to issue task order contracts to supplement the work ORAU is doing, authorize ORAU to bring in others who don't have conflicts of interest, let's allocate more funds if there wasn't enough money budgeted from our friends to come over from the Labor Department to you all to solve But let's not tear down the conflict of that problem. interest wall. Let's apply the resources where they're needed so that at the end of the day there is no question about the integrity of the product you put out. And if you start to tank the integrity of your product at the outset, what a shame this program is going to turn into.

10

11

12

13

14

19

16

17

18

19

20

21

DR. ZIEMER: Okay. Thank you, Richard, certainly good food for thought for us.

Now are there any other members of the public who wish to comment? Again, we're eating -- my mind must be -- we're eating into our -- into our lunch hour.

Okay. We will take -- let's try to be back here by 1:15, because we have to finish up by 2:00. Okay? (Whereupon, a luncheon recess was taken.)

REVIEW/APPROVAL OF MINUTES, BOARD WORK SCHEDULE & ADMINISTRATIVE HOUSEKEEPING

DR. ZIEMER: If you haven't already done so, Board members, there is a green slip that you need to fill out if you're going on the tour to Oak Ridge facilities today. Where it says estimated dose for the year, I had all kinds of thoughts about how you might figure that out -- put in a -- you know, a mean value with -- tell them whether it's a lognormal distribution and -- and the error bars. Anyway, fill everything in that's highlighted there and pass that over to these young ladies who are here from the Lab to help with the logistics.

We have -- let's see, who's missing? Mike? Mike told

me he had to leave, and Jim isn't here anyway. Let's see, Tony is -- okay. Well, I think we'll sort of go ahead here anyway.

We have two immediate things to take care of. We need to take action on the minutes of the previous meetings, or some of the previous meetings, and then we also need to identify some dates for our next meeting, and there may be some other housekeeping things. But let's first address the minutes, the first set of which are the minutes for February 5 and 6. They are stamped draft, 5/19/03, which means they were the draft for this packet, but they are the minutes for February 5th and 6th. Now there are -- there was a previous set in your packet that is not stamped draft. That's not the set we're focusing on, unless somebody wishes to revert to that earlier version. But the Chair would entertain a motion to approve these minutes. Is there a second?

DR. DEHART: Second.

DR. ZIEMER: Let me ask for any corrections or additions, with the exclusion of minor spelling and other editorial things which you can pass on separately to Cori. But are there any substantive changes in the

minutes that anyone wishes to point out?

If there are none, are you ready to vote on the acceptance of these minutes or what we're calling summary minutes?

UNIDENTIFIED: Yes. Yes.

DR. ZIEMER: Okay. All in favor of accepting these minutes say aye.

(Affirmative responses)

DR. ZIEMER: Any opposed say no.

(No negative responses)

DR. ZIEMER: Any abstentions?

10

11

12

13

14

15

16

17

18

19

20

21

22

(No responses)

DR. ZIEMER: Thank you. We have approved those minutes.

We also have in the packet summary minutes -- this one happens to be labeled summary report, for some reason; I'm not sure if there's a difference -- for the March 7th meeting. This would be the meeting in Cincinnati March 7th, and likewise the Chair would entertain a motion to accept these minutes.

UNIDENTIFIED: So moved.

MR. PRESLEY: Second.

DR. ANDERSON: The only thing I would say is it's helpful to have the pages numbered.

DR. ZIEMER: Yes, I noticed that myself. In fact, it was my recollection that the version that I saw on my computer had them numbered, you know, with the header/footer business. But they somehow either didn't show up in the printing or in the transmission, but we will make sure that the copy that I -- I have to sign off on these, and I'll make sure that those are.

DR. ANDERSON: And single-spaced, too.

DR. ZIEMER: That's why these were so long.

DR. ANDERSON: Yeah, I was going to say that looks awful long, but it isn't. It's just that --

DR. ZIEMER: Actually we've already had a discussion on single versus double space on future minutes and they are going to be single-spaced. I had arbitrarily made that decision already, so -- but the final form will be single-spaced. The draft -- doesn't matter to me, but

DR. ANDERSON: I think it's helpful if it's double-spaced 'cause you can write on it then -- for the draft. And that can also help us distinguish between

final and draft.

DR. ZIEMER: Oh, you mean for the draft that comes to you?

DR. ANDERSON: Yeah.

10

11

12

13

14

15

16

17

18

19

20

21

22

DR. ZIEMER: Okay, that would be fine. We'll -- we'll do -- and our editor/writer is nodding because he's going to help us with that, so we'll have the drafts in double-space and the final form will go to single. Are there corrections or additions to the March 7th minutes? Apparently not.

All in favor of accepting these minutes will say aye.

(Affirmative responses)

DR. ZIEMER: Any opposed say no.

(No negative responses)

DR. ZIEMER: The minutes -- any abstentions?

(No responses)

DR. ZIEMER: The minutes are approved. Thank you very much.

We actually have two additional sets that will be coming to you, and we can handle them at our next meeting, but those are the minutes of our two telephone conferences which were I think March 14th and 28th,

something like that.

10

11

12

13

14

19

16

17

18

19

20

21

22

Okay. Administrative housekeeping, one of the things we need to do is talk about dates for next meeting. То sort of kick that off, let me identify one of the issues that -- the most immediate issue I think that has to come before us for action will be the materials that were presented to us earlier by Mark, and that is the various documents relating to the task orders and the work group procedures. It would be useful if we had the task orders ready to go at the time that the final contract is awarded, and it's anticipated that that would actually occur perhaps in September. that would suggest that we ought to meet no later than perhaps August. We could meet in July. I see no need to meet in June. I'm not sure we would need to meet in July, but it's going to depend somewhat on schedules. I know that August starts to get busy in a variety of ways in terms of people's family commitments and school and things like that, but -- or last minute vacations, whatever it may be. But let me ask -- let me start with the staff, because I think we also need to recognize as the staff pushes forward in terms of their

activities and other commitments, what does it look like from staff point of view? Is July probably not a good time?

MR. ELLIOTT: Probably not a good time in July, and there's at least -- I have Dr. Melius's availability, as well, and I'm looking at that. And Mike Gibson told me that whenever you set the meeting, he'll be there since he's now enjoying his non-retir-- non-employment, I guess. I don't think he's retired, per se, but there's one week in August I can point to, August 11th through the 15th, that would not be good. August 20th through the 22nd would not be good for Dr. Melius. I think Cori's got a week in there in August.

MS. HOMER: Late July/early August, yes.

DR. ANDERSON: How about the week of the 25th of August?

MR. ESPINOSA: The 26th is out for me, that week.

MR. GRIFFON: I would rather have it earlier in August, just so we can finalize these things. We might need...

DR. ZIEMER: Well, let's go back and just check dates in August. Let's begin with the first week in August, which is the week of August 4, I guess.

| 1 | DR. DEHART: I'm out 3, 4, 5. |
|----|--|
| 2 | DR. ZIEMER: Three, 4, 5 is out. |
| 3 | DR. ANDERSON: And I'm out 7 and 8. |
| 4 | DR. ZIEMER: I'm out 8 and 9. |
| 5 | DR. ANDERSON: How about the week before? |
| б | DR. ZIEMER: Last week of July? |
| 7 | UNIDENTIFIED: Cori's out. |
| 8 | DR. ANDERSON: Oh, that's yours, yeah. |
| 9 | DR. ZIEMER: Cori's out the last week of July. |
| 10 | MR. ESPINOSA: What about the 21st of July? |
| 11 | DR. ROESSLER: That's the Health Physics |
| 12 | DR. ZIEMER: Health Physics meeting. |
| 13 | DR. ROESSLER: There are a lot of health physicists on |
| 14 | the staff that are going. |
| 15 | DR. ZIEMER: Yeah, I'm involved there and couldn't make |
| 16 | it. You're probably involved. |
| 17 | MR. ESPINOSA: Is the 14th getting a little bit too |
| 18 | soon? |
| 19 | DR. DEHART: Week of the 11th sometime? |
| 20 | MR. ESPINOSA: July or August? |
| 21 | DR. DEHART: August. |
| 22 | MR. ELLIOTT: August 11th is out. That week is out. |

So

DR. ZIEMER: August 11th, that whole week is out? MR. ELLIOTT: Yes. DR. ZIEMER: Okay. What about the 18th and 19th of August? MS. HOMER: far I haven't heard any no's to that. DR. ANDERSON: That's good for me. MR. ESPINOSA: I thought that was bad for --MR. GRIFFON: What was that date? DR. ZIEMER: 18th or 19th. MR. GRIFFON: Of August? DR. ANDERSON: Monday/Tuesday. MR. ESPINOSA: That's a little bit bad for me, but I might be able to rearrange it. DR. ZIEMER: I have a cryptic notation. I'm going to ask if Mrs. Ziemer has returned from lunch. We're

UNIDENTIFIED: What's it say?

okay? Okay.

10

11

12

13

14

15

16

17

18

19

20

21

22

DR. ZIEMER: Something like check with wife before you do anything. Not quite that. No, I had -- I had an item which was only tentative and my wife has signaled that it's clear that week.

MR. ELLIOTT: Could we -- instead of Monday, could we

look at Tuesday/Wednesday or --DR. ZIEMER: 19/20? MR. ELLIOTT: Yeah. 20th through the 22nd is out. MS. HOMER: DR. ZIEMER: Who has a conflict on the 20th? MS. HOMER: I thought Dr. Melius might have. MR. ESPINOSA: I think Dr. Melius did and --MR. ELLIOTT: Yes, he has a conflict on the 20th, 21st and 22nd. 10 MR. ESPINOSA: It's getting up to July --11 DR. ZIEMER: Is the 18th bad, also? MR. ESPINOSA: 18th and -- it's not bad, but the 19th 12 is kind of bad for me. 13 DR. ZIEMER: Okay. 14 15 UNIDENTIFIED: But is it possible? MR. ESPINOSA: With this much notice, it's possible. 16 I'll just have to bring her along. 17 DR. ANDERSON: That's fine. 18 19 DR. ZIEMER: There you go. 20 DR. ANDERSON: Where would you like to meet? 21 DR. ZIEMER: Okay, 18th and 19th are possible. Let's -22 - what happened on the week of the 25th? Is that --

MR. GRIFFON: I just thought that was kind of late, given that I have -- you know... DR. ZIEMER: But poss--MR. GRIFFON: But possible for me. DR. ANDERSON: Yeah, it's okay for me. DR. ZIEMER: In terms of actual meeting time, is it --25, 6, 7, any conflicts that week? MR. ELLIOTT: 26th and 27th? MR. ESPINOSA: 26th and 27th are out for me. 10 DR. ZIEMER: Are... 11 MR. ESPINOSA: The 26th and -- 26th and 27th I'm not available. 12 DR. ZIEMER: Okay. So that means if we did it that 13 week it would have to be the 28th or 9th. Okay. 14 15 the possibilities then, it appears, are the 18th and 19th or the 28th and 9th. 16 DR. ANDERSON: That's just before Labor Day? 17 18

DR. ZIEMER: Yes, that is just before Labor Day.

DR. DEHART: Let's go for 18th/19th.

DR. ANDERSON: 18/19.

DR. ZIEMER: 18/19?

19

20

21

22

DR. ANDERSON: We'll just squeeze Richard here.

DR. ZIEMER: Okay, 18th and 19th is where we have settled. Cori --I'm okay on the 18th and 19th. MS. HOMER: Is there anything wrong with the week of DR. ANDRADE: July 14th? MR. ESPINOSA: Yeah, I was just going to say the same -DR. ZIEMER: I have a conflict on the 14th, 15th and 16th. 10 MR. GRIFFON: I'm out the 14 --11 MR. ESPINOSA: What about --MR. GRIFFON: -- 14 through 17. 12 MR. ESPINOSA: -- the 17th and 18th? 13 14 DR. ZIEMER: You're out the whole week through the 15 17th. DR. DEHART: I'm out the next. 16 DR. ZIEMER: Okay. 17 DR. ANDRADE: Of July or --18 That was July we were looking at. 19 DR. ZIEMER: 20 looks like we're back to August 18th and 19th. 21 MR. ESPINOSA: Getting into the 7th would probably be 22 too -- too close.

MR. GRIFFON: July 7th, you mean?

MR. ESPINOSA: Yeah.

MS. HOMER: That's not much more than a month away.

DR. ZIEMER: Let's shoot for August 18/19. We need to then also decide where we should meet.

MR. GRIFFON: St. Louis? St. Louis is an option.

Hanford is an option.

MR. ESPINOSA: Hey, I thought it was my decision. Oh, I'm sorry.

DR. ROESSLER: Las Vegas.

10

11

12

13

14

15

16

17

18

19

20

21

22

MR. ESPINOSA: There you go, Las Vegas. No, no, that's -- that'd get me in trouble.

DR. ZIEMER: Let me ask -- I want to ask Mark, in terms of the working group, is there any need for us to be in Cincinnati for this meeting in terms of logistically -- in terms of what the work group is going to be doing, to prepare or...

MR. GRIFFON: I -- I don't know. I guess there could be some advantages to it. I'm not sure we need to get access to the database systems or anything like that at this point.

MR. ELLIOTT: It would certainly be easier on staff, I

can tell you that. MR. ESPINOSA: St. Louis? MR. PRESLEY: No, Cincinnati. MR. ESPINOSA: Oh, Cincinnati? MR. ELLIOTT: But I serve at your pleasure, so... DR. ZIEMER: Other suggestions? DR. ANDERSON: Where would you like to go, Cori? MS. HOMER: Me? DR. ANDERSON: Yeah, where would you like to go? 10 MS. HOMER: I like Santa Fe. 11 MR. ESPINOSA: Yeah, how about Santa Fe? MS. HOMER: That works for me. 12 MR. GRIFFON: St. Louis is great in the summer. 13 MR. ELLIOTT: So's Cincinnati. 14 15 DR. ANDERSON: Or maybe Atlanta. MR. GRIFFON: Warm and humid. Right? 16 17 DR. ANDERSON: Savannah. Savannah, right. DR. ZIEMER: Well --18 MR. ESPINOSA: Before we commit, does anybody have a 19 20 baseball schedule? 21 DR. ZIEMER: Let me suggest a couple of considerations. 22 The one was whether or not there is a logistical

reason to meet in Cincinnati. There could be some staff considerations, that is one. Another possibility was to go back to the D.C. area, and then the other possibility would be to try to hit a city that is in fact co-located with one of the sites, which would argue for either one of the DOE sites or one of the other sites, such as -- such as Mallinckrodt.

MR. ESPINOSA: With a -- reading some of the public comments on the SEC, you know, from a year ago and the stakeholders meetings and stuff like that, I would like to see the Board at some time go to the Hanford area, and I don't know if it's -- you know, and also a consideration, Ms. Wanda Munn, she's traveled through all the time zones and we haven't gone to hers.

MS. MUNN: Honey, you're welcome to come on down any time. In the middle of August we are hot to trot.

It's -- I would --

MR. ESPINOSA: Maybe -- how is it in October there, Wanda?

MS. MUNN: I really, genuinely would love to have you there, but I am concerned about the overall cost of transporting everybody across country like that. It's

bad enough transporting me across. Every time I look at my ticket, I blanch. But the concept of bringing this entire Board and the staff out there is -- you know, I think we need to go out there at some juncture, but it really is going to cost us a lot.

MR. ELLIOTT: If I might add this, I think it would be appropriate when we have the technical basis document, site profile for Hanford, that's when we probably ought to go out there and --

MR. ESPINOSA: Yeah, that's a good --

MR. ELLIOTT: -- talk about that, deliver that, you know, get the Board's input on that once we have it in a state where we're ready to present it to you.

DR. ANDRADE: I would think that would be a good -DR. ZIEMER: Are there any other locations where we're
approaching that, where it would be appropriate to go
to such a location? Any other DOE sites or other major
facilities?

DR. ANDRADE: Based on public comment, I think there's
a --

UNIDENTIFIED: Microphone.

MR. ELLIOTT: Microphone, please.

DR. ANDRADE: Based on public comment, I think there's a lot of interest in St. Louis, what's going on at Mallinckrodt -- the former Mallinckrodt facilities. It's centrally located. It would probably be easy for all of us to get to, so I -- I'd suggest that as a -- as a potential place for the 18th.

MR. ESPINOSA: Make it a motion.

DR. ZIEMER: Any other suggestions?

DR. ROESSLER: I'll say that since there's no place that's good to go in August that we might as well go to Cincinnati and save St. Louis for when we can do a little sight-seeing and Hanford when it's -- the weather's better. That's just my...

MR. ESPINOSA: What about Lawrence -- is it Lawrence Livermoor?

UNIDENTIFIED: California.

MR. ESPINOSA: Yeah, what about California this time of year? The Giants are playing.

DR. ZIEMER: Robert?

10

11

12

13

14

15

16

17

18

19

20

21

22

MR. PRESLEY: Larry, would it help if we came to your place in August to straighten up some of our problems that it looks like that we're going to be perceived

with our audit? That way we'll get more of the staff.

MR. ELLIOTT: I think if you could meet in Cincinnati in August, it would be of benefit to everybody. It would allow my staff to do the work that they need to be doing in the office. It will allow us to support your needs if you've got information needs on developing your process or, you know, checking out the technical basis documents that we might have at the ready at that point. We need to figure out in this process how we can get the information on these administrative records to you and -- it'll travel less staff if we can do it right there, but...

MR. PRESLEY: Can I make a motion we go to August -- go to Cincinnati in August?

DR. ZIEMER: Sure. Hang on, we'll hear from Richard and then you can make a motion.

MR. ESPINOSA: In the March meeting it was also suggested -- if I'm not mistaken, it was suggested by Mr. Presley here, that the rest of the Board go through the -- ORAU's office, the training, and NIOSH offices, as well, so we might want to make it a three-day trip for the people that aren't on the working group, the

people that are alternates on the working group. So that's something that might want to be considered now.

MR. PRESLEY: Might want to do it all for everybody 'cause things have changed. Everybody hears the same thing at one time.

MR. ESPINOSA: And I think it -- yeah, just like -everybody hear the same thing at one time. I know
that's a problem with (inaudible) and stuff like that,
but even if we broke it into two groups, one group in a
half-day in the morning and a half-day in the
afternoon, it's -- you know, this meeting might want to
be turned into three days instead of just the general
two.

DR. ZIEMER: That's a good suggestion. I think we could work out the logistics on that. You want to make your motion now, Mr. Presley?

MR. PRESLEY: I make a motion we go the 18th, 19th, possibly the 20th to Cincinnati in August.

DR. DEHART: Second.

DR. ZIEMER: And seconded. Further discussion?

MR. ELLIOTT: Just so you know, Dr. Melius would not be available on the 20th, so if you target the meeting for

the 18th and 19th and then the training -- the working session for those who could stay on the 20th --

MR. ESPINOSA: Are you seeing a full two-day schedule, Larry?

MR. ELLIOTT: Well, I was going to ask, what -- you know, what other agenda items you want to see on that meeting date. You know, we could certainly approach Dr. Till and see if he is available those two days to come in and talk to you all about the NAS report. That's one thing --

DR. ZIEMER: We'd want to hear that. We need to finalize these documents. Those are --

MR. ELLIOTT: This is the primary work.

DR. ZIEMER: -- the two main issues, and it may be that we'd have a day and a half meeting plus the training.

DR. ANDRADE: I think beyond -- beyond the agenda items, I know that there are four of us that still require the training -- we're alternates -- and that does include Jim, Leon, Wanda and myself.

MR. ESPINOSA: You're on there, too. Right, Henry?

DR. ANDERSON: Yeah. Well, I mean eventually

everybody, so it would be nice if we kind of put it

together, we all go through.

DR. ZIEMER: Let me suggest that we plan the following -- we'll plan it to be a day and a half meeting, plus the training. But if the agenda fills up, we have the option of going over the extra day. Is that --

MR. ELLIOTT: Yes, you would. But I would offer this for your consideration, that to have the whole Board there to go through what the working group has seen --

DR. ZIEMER: Oh, we'd need to --

MR. ELLIOTT: -- constitutes a quorum, constitutes -- we'd have to have a closed session because you're going to deal with Privacy Act information and we'll have to get that put in play to have a closed session of the Board.

MR. ESPINOSA: Just another suggestion --

MR. ELLIOTT: Or you could split the group and split the days. That's the other way to get at it.

MR. ESPINOSA: Yeah, just another suggestion, you know, some people won't be leaving until that Wednesday the 20th, so maybe we could have a half-day on the 20th and some people get here early enough to where you can have a later half-day on the 18th or something -- or in the

morning of the 18th and, you know, however that works out.

DR. ZIEMER: And start mid-day on the 18th, yeah.

Yeah, we can work out the logistics. I think we understand the -- so did we vote on this? I lost track here.

MR. PRESLEY: Yes.

10

11

12

13

14

15

16

17

18

19

20

21

22

DR. ZIEMER: We did. Did we? We didn't vote.

DR. ANDRADE: No, I don't think so.

DR. ZIEMER: Must be time to end. All in favor of meeting on the 18th through the 20th, if necessary, in Cincinnati say aye.

(Affirmative responses)

DR. ZIEMER: Any opposed?

(No negative responses)

DR. ZIEMER: So ordered. Thank you very much.

DR. DEHART: One other question, Paul.

DR. ZIEMER: A question.

DR. DEHART: When will the final rule be out? Do we have any idea?

MR. ELLIOTT: Good question. We are addressing the comments that we received and we're working that rule

back together, and it's our hope that before the end of the year we'll have a final rule out and people can --DR. DEHART: Okay, so August is too -- it's premature.

MR. ELLIOTT: Yes, yes. The number of comments that we've got and the number of issues we have to deal with, I don't think we're going to have a final rule by August.

DR. ZIEMER: Mark, did you have a --

MR. GRIFFON: Yeah, just another proposed agenda item.

I'd like to see the site profile -- you know, status
report on site profiles --

MR. ELLIOTT: Sure.

10

11

12

13

14

15

16

17

18

19

20

21

22

MR. GRIFFON: -- at the meeting if we can, and if possible maybe a presentation on sample ones that have been completed. I know Bethlehem Steel's one -- I guess you're calling it an exposure profile more than a site profile, but --

DR. ZIEMER: Did you have another comment, Rich?
MR. ESPINOSA: Oh, I just -- you know, I was
(inaudible).

DR. ZIEMER: Okay. Any other items pertaining to the next meeting?

Okay, housekeeping items. Cori?

Instead of filling out that little MS. HOMER: Yes. slip of paper we usually ask you to hand to Larry and have him sign to approve your time, what I'd like for you to do from now on and in the future, to send an email to Larry identifying very specifically the time you've spent preparing, time you've spent on the work group and of course our meeting time we already know, you know, what days you were here. That way when I'm accounting for your time, I can separate the work group and prep time, as well as meeting time. But go ahead and send it to Larry. He'll approve it and send it to me. You'll have to do that the day that you get back or the day after or I may not be able to get you on that pay cycle.

MR. ESPINOSA: You want the meeting time, also?

MS. HOMER: No, I do not need the meeting time.

DR. ROESSLER: So you need it -- two categories, the preparing for the meeting and doing the normal things, and then the other one is --

MS. HOMER: Work group.

10

11

12

13

14

15

16

17

18

19

20

21

22

DR. ROESSLER: -- work group. Okay.

MS. HOMER: Anything work group-related is entirely separate from preparation time.

MR. ELLIOTT: And if you've already given me this on a piece of paper, don't send an e-mail at this time, but for the future that's the way we'd like to have this transaction occur.

DR. ZIEMER: Cori, for clarification, the work group time, you're -- you're talking about the actual time that the work group meets.

MS. HOMER: Meets, as well as whatever time you spend preparing for the work group, 'cause it's entirely different.

MR. GRIFFON: Entirely.

10

11

12

13

14

15

16

17

18

19

20

21

22

DR. ZIEMER: It's separate from the committee time.

MS. HOMER: I know, it's -- the way I have to account for it on annual reports, it's just really helpful for me to have it as specific as possible.

MR. GRIFFON: Just a clarification, Cori, on the prebid meeting that a bunch of us attended, were we supposed to submit ours or was --

MS. HOMER: Yes.

MR. GRIFFON: Okay, I never did --

DR. ZIEMER: For prep time --MS. HOMER: Uh-huh. DR. ZIEMER: -- and the meeting time? MS. HOMER: Uh-huh. No, meeting time you never have to DR. ZIEMER: Okay. MS. HOMER: -- but if you have attended a work group meeting, and I may not necessarily be aware of that, you need to tell me. 10 MR. ESPINOSA: Yeah, the bidder's conference was 11 considered a work group meeting. Right? MS. HOMER: Okay, so identify that under work group. 12 13 MR. ESPINOSA: Okay. MS. HOMER: Even if I was there, just go ahead and --14 15 DR. ZIEMER: Thank you. Other items --MS. HOMER: 'Cause that helps. 16 DR. ZIEMER: -- Cori? 17 MS. HOMER: I think that's about it. Can you think of 18 anything else? 19 20 DR. ZIEMER: Henry -- or Jim -- Henry. 21 DR. ANDERSON: It might be helpful if, just seeing the

difficulty picking a date for the -- for this next

22

meeting, when we get into the fall season, when I look at my calendar it's already filling, so I'm wondering if we want to start to think about anyway what -- when would the next meeting potentially be and -- something like that 'cause, for instance, my October -- that's always the busiest month, so...

MS. HOMER: I can pull them by e-mail.

DR. ZIEMER: Cori, why don't you ask each person to send in their schedule --

MS. HOMER: Yeah.

10

11

12

13

14

15

16

17

18

19

20

21

22

DR. ZIEMER: -- of bad times --

MS. HOMER: Through October and November, is that helpful? Okay. So if you could send your schedule to me through November.

DR. ZIEMER: Now -- you have a calendar in your packet now -- right? -- if you know what it is.

MS. HOMER: That's right.

DR. ZIEMER: Otherwise e-mail it?

MS. HOMER: Uh-huh.

DR. ZIEMER: Any other items to come before us today?

Okay. Does anyone have any other issue that needs to be raised? I have some instructions on the tour.

Robert?

10

11

12

13

14

MR. PRESLEY: People that are going on the tour please just stay in place here in the room and Steve White will come in and we will get our instructions on badging and then we'll head out and get on the bus.

Has everybody got a blue TLD that's going on the tour?

DR. ZIEMER: Okay, very good. And again for the record, I want to announce that the tour is simply an effort to allow Board members to see the site and learn more about the Oak Ridge site. There will be no official business conducted by this Board on the tour. We stand adjourned.

(Meeting adjourned 1:50 P.M.)

CERTIFIC

ATE

STATE OF GEORGIA)
COUNTY OF FULTON)

I, STEVEN RAY GREEN, being a Certified Merit Court
Reporter in and for the State of Georgia, do hereby certify
that the foregoing transcript was reduced to typewriting by
me personally or under my direct supervision, and is a true,
complete, and correct transcript of the aforesaid
proceedings reported by me.

I further certify that I am not related to, employed by, counsel to, or attorney for any parties, attorneys, or counsel involved herein; nor am I financially interested in this matter.

WITNESS MY HAND AND OFFICIAL SEAL this ____ day of June, 2003.

STEVEN RAY GREEN, CVR-CM GA CCR No. A-2102

| 46 | 0 |
|----|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |